UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

CENTOCOR ORTHO BIOTECH, INC.,	)	
	)	
Plaintiff,	)	No. CV 08-3573 MRP
	)	
v.	)	
	)	
GENENTECH, INC., et al.,	)	
	)	
Defendants.	)	

TRANSCRIPT OF PROCEEDINGS

THE HONORABLE MARIANA R. PFAELZER

SENIOR U.S. DISTRICT JUDGE PRESIDING

LOS ANGELES, CALIFORNIA

AUGUST 17, 2010

MOTIONS HEARING

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United States Courthouse
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Internal File No. 10061

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TUESDAY, AUGUST 17, 2010; 11:00 A.M.

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THE CLERK: In the matter of Calendar Item No. 1, Case No. CV 08-3573, Centocor Ortho Biotech, Inc. v. Genentech, Inc.

Counsel, please state your appearances for the record.

MS. ELDERKIN: Good morning. Your Honor. Dianne Elderkin on behalf of Centocor Ortho Biotech and the counterclaim defendants. And here with me are my partners, Barbara Mullin and Steve Maslowski, and we'll be sharing duties today on handling the arguments.

MS. DURIE: Good morning, Your Honor. Daralyn Durie appearing on behalf of Genentech. Also present are Mark Pals and Adam Brausa from Kirkland & Ellis --

THE COURT: Yes.

MS. DURIE: -- also appearing on behalf of Genentech. Present, also, are Gary Loeb and Laura Storto from Genentech.

MR. GINDLER: David Gindler and Joseph Lipner of Irell & Manella on behalf of City of Hope.

MR. LIPNER: Good morning.

THE COURT: We're going to start with this motion that you made, Ms. Durie, about Dr. Wall. Shall we do that?

MS. DURIE: Yes.

THE COURT: Before you get started, let me say -- and this has no -- this doesn't favor either side. I'm just -- I'd just like to observe that I have tried hard to understand the points that Dr. Wall was apparently making, and I have tried hard to see how they relate to particular issues, but because they came in the way in which they did, I'm not positive that I have a total fix on it.

So in the course of your talking about this, let's see what you think the testimony would be used for. It is quite -- it has been quite hard for me to answer the question, what is that paragraph -- what issue that paragraph of what he says is pointed at. I can't do better than that.

MS. DURIE: Okay. Thank you, Your Honor. And I appreciate that guidance.

Let me start by making one global observation that I think cuts across many of the opinions that Dr. Wall has rendered. Centocor's primary complaint in its opposition to this motion appeared to be that we had taken Dr. Wall's deposition testimony out of context, and that based on what I characterized as those snippets of deposition testimony, that the Court was not in a position to evaluate the significance of Dr. Wall's testimony as a whole.

Now, as this Court is well aware, we did in fact

provide the entirety of Dr. Wall's deposition transcript to the Court.

THE COURT: And I read it. I read it twice.

MS. DURIE: Understood, Your Honor.

And, therefore, the Court did have an opportunity to assess Dr. Wall's testimony in toto.

THE COURT: Let me interrupt you now and remind you of what I said at the beginning. I now have some testimony by way of declaration or report which doesn't exactly fit into the deposition testimony. Isn't it in addition to what -- I should put it directly.

Did you know exactly what he was going to say in toto when you took his deposition?

MS. DURIE: No. And certainly I did not know that I would be unable effectively to cross-examine him with respect to the bases for some of his opinions --

THE COURT: Yes.

MS. DURIE: -- or the significance of statements that were included in documents cited and discussed in his expert report because Dr. Wall had failed to review those documents.

And the reason that I started where I did, I thought it was an interesting observation on Centocor's side, because in fact the precise problem with Dr. Wall's testimony as a whole is that he did not have the opportunity

that this Court had to review the underlying record about which he was opining in its totality.

He was, instead, merely provided with selected excerpts from depositions and was not able in evaluating the significance of that testimony to view it in context. And that is the most fundamental problem with Dr. Wall's testimony.

It's one thing if the issue is whether the expert in selecting the facts upon which that expert will rely decides to ignore certain facts or that certain facts are not germane to his analysis. In that situation there is a methodology that can be critiqued and that can be cross-examined. But the fundamental problem here is that the process was backwards.

Rather than being presented with documents to review where he could weigh the significance of the evidence and select that evidence which he deemed germane to his analysis, Dr. Wall was essentially presented with a fait accompli, and it is -- it is that that the courts have refused to countenance.

So in Atenol (ph), for example, the Court excluded testimony where the expert had not surveyed the field in order to reach his own opinions but was just relying on his own unrefreshed recollection. We pointed the Court to the *Rockwell* case where the expert relied on digests of medical

histories rather than reviewing the underlying medical histories themselves.

And as the Court said in *Rockwell*, a proffered expert has to bring more to the jury than the lawyers can offer in argument, and that, I think, Your Honor, is the -- is the common thread that underlies each of the opinions that Dr. Wall has proffered.

The fact that he has even exemplary qualifications and that he is a very experienced witness --

THE COURT: He certainly has qualifications.

MS. DURIE: He does, and he is very experienced, and he's well-familiar with this process, but that is not a substitute for his performing his own analysis.

Now, with respect to the specific opinions that Dr. Wall has offered, first, he does offer an opinion on claim construction --

THE COURT: Yes, he does.

MS. DURIE: -- and on what he considers the appropriate scope of the claim to be. However, he did not review the file history in reaching that conclusion, nor did he review the record of the reexamination, nor did he understand the issues to which the reexamination was addressed.

And for that reason alone, in addition to all of the various reasons for which expert testimony is disfavored

in the claim construction process more generally, Dr. Wall should not be permitted to offer either to this Court or to a jury any opinion with respect to the meaning of the claims.

Now, Dr. Wall also has a set of opinions on the subject of obviousness-type double-patenting, and here the fundamental -- there is one problem that stems from the report and there is a different problem that stems from the deposition.

The problem that stems from the report is that the standard for obviousness-type double-patenting that Dr. Wall purported to apply in the report is wrong. In other words, the obviousness-type or nonstatutory double-patenting inquiry looks to comparing the scope of two claims and whether one is an obvious variant of the other. It is not an unbounded exercise in surveying the prior art.

We are aware of no court that has adopted the type of obviousness-type double-patenting test that Centocor is proposing in Dr. Wall's report. And, logically, there's a good reason why that can't be the correct test. Because if it were possible simply to take the claims of the earlier patent and combine them with all of the various prior art references that are otherwise in play for purposes of a conventional obviousness analysis and label that as obviousness-type double-patenting, without focusing

specifically on the scope of the claim, then in every case where there was a prior patent, the defendant would be able to transform an obviousness case into an obviousness-type double-patenting case simply by adding the prior claims into the equation.

And the consequence of that would be, among other things, that the defendant would argue that secondary considerations of nonobviousness, for example, were no longer in play.

That -- that cannot be correct. And that is why in the context of nonstatutory double-patenting the courts have always focused very carefully on claim scope and not simply on a traditional prior-art-based obviousness analysis. And yet in his report, Dr. Wall does not specifically compare the scope of the claims.

Now, this became even more apparent at his deposition where Dr. Wall admitted that he had no opinion as to whether, for example, one could infringe the claim of the '567 patent without infringing the claim of the '415 patent or vice versa, and I think that right there is a sufficient reason for the Court to preclude Dr. Wall from offering the obviousness-type double-patenting opinion that is set forth in his report.

Now, there was a second problem that became apparent only at his deposition which is that Dr. Wall did

not understand the obviousness-type double-patenting opinion that had been set forth in his report. And when I endeavored to cross-examine him about the significance of the prior art in that context, he in fact indicated that, so far as he knew, the double -- the prior art was not even relevant to his opinion, and -- and therefore he was unable to be effectively cross-examined even with respect to the opinion that was set forth in his report.

So I think for each of those reasons, both the problem with the legal standard in the report and the fact that Dr. Wall was unable at his deposition even to articulate what it was that he had supposedly said in his report --

THE COURT: Well, it was not a satisfactory deposition, but let me ask you this -- I agree about that. What about infringement?

MS. DURIE: So I think there is a predicate problem with respect to Dr. Wall's opinion on infringement, which is the claim construction question --

THE COURT: Yes.

MS. DURIE: -- that we will be addressing. And I don't think Dr. Wall should be permitted to offer any testimony on that claim construction issue to the extent that that is embedded in and a predicate for, which I think it is, his ultimate conclusions with respect to

infringement.

THE COURT: There is a further problem which is that the file history of the patent is relatively clear about that term.

MS. DURIE: I think that's right, Your Honor.

THE COURT: The term that he's talking about.

MS. DURIE: That's right. Dr. Wall -- in offering his noninfringement opinion, Dr. Wall is focused on the limitation of -- that the molecules must be produced as separate molecules.

THE COURT: Yes.

MS. DURIE: Now, we're going to discuss in the context of Centocor's summary judgment motion, I expect, the significance of that language, but the Court is correct that that language cannot be understood divorced from the file history of the patent, which is lengthy.

THE COURT: Almost nothing can be understood without looking at the file history.

MS. DURIE: That --

THE COURT: It is a daunting job, but you have to do it.

MS. DURIE: That is absolutely correct, and that is, Your Honor, why I began this morning where I began, which is that Dr. Wall's failure to have reviewed the file history infects his ability to offer well-thought-out and

methodologically sound opinions across such a range of topics because he has been deprived or chosen not to avail himself of critical information in formulating those opinions.

Now, with respect to written description, we have some of the same concerns that are at play in obviousness-type double-patenting, and some additional concerns as well.

First, here, too, of course, Dr. Wall failed to review the file history in order to understand the way that the patent office interpreted the claims and what the patent office understood to be disclosed.

Dr. Wall also applied an incorrect standard for what constitutes written description. This is one of the places where Centocor complains that we were unfair to Dr. Wall in our selection of his testimony. But the Court has had the opportunity to see the back-and-forth exchange with respect to Dr. Wall's understanding of written description, and I think it is apparent from the entirety of that exchange that Dr. Wall did believe that in order to satisfy the written description requirement, the inventors had to demonstrate that they had actually reduced the invention to practice.

Now, in this case they had, but that sort of fundamental error of what is the correct standard then

infected Dr. Wall's ability to evaluate the significance of other disclosures in the patent.

The other problem with Dr. Wall's analysis of written description is that he purports to rely on deposition testimony, on excerpts from the reexamination record, and on portions of documents that Dr. Wall freely admitted that he never read. Precisely because his failure to have read those documents means that he cannot have evaluated that testimony in context and therefore cannot meaningfully be cross-examined about it, he should not be permitted to offer an opinion that relies on those sources of evidence.

And -- and, you know, there are a number of examples of this. One example is his reliance specifically in the context of written description on three lines from Dr. Riggs's deposition, admitting that he was not even aware that the testimony had been given in a different case and did not have the opportunity to see Dr. Riggs's explanation of that testimony in this case.

Another example his is reliance on Dr. Holmes's deposition testimony where the report contains a parenthetical characterizing that deposition testimony, but Dr. Wall admitted he didn't even know who Mr. Holmes was.

It's -- the problem here is twofold. It is the fact that Dr. Wall did not do the work of an expert in

selecting that testimony and making a determination reading through the record that these were the things that supported his opinion and that his opinion was justified on the basis of the record as a whole, and therefore he did not do the work of an expert, and, secondly, that the consequence of Dr. Wall having simply been fed these excerpts of record rather than having reviewed the record himself is that it precludes the ability effectively to cross-examine him.

Now, the next sort of category of opinions that Dr. Wall has to offer have to do with the prior art and the significance of that prior art, be it in the context of anticipation or be it in the context of obviousness. And here, too, the problem is what Your Honor previously identified sort of in a nutshell, that Dr. Wall did not review the file history and he did not review the reexamination record, and he therefore has not grappled with the way that the PTO assessed the significance of that prior art and why it is, either in the first instance or in the second instance at the conclusion of the reexamination, that the patent office made a determination based on this same prior art upon which Dr. Wall is relying that the claims of the patent should issue.

And that is important because each of the references here, whether it's Rice and Baltimore, Oy (ph), Ochi, Axel, are references that were before the Patent and

Trademark Office, and Dr. Wall should not be permitted to insulate himself from examination with respect to the PTO's determination of those references by failing to review the record.

Certainly Dr. Wall should not be able to offer an opinion, as he does in his report, that the Patent and Trademark Office did not consider whether Axel anticipates the claims of the '415 patent both because that is incorrect as a matter of law, since Axel was before the office and they, therefore, did have an obligation to consider whether that art was anticipatory, but also because Dr. Wall cannot possibly have any basis for expressing that view having failed to read those underlying documents.

And so I think, Your Honor, in each case we come back to what is at its core the same fundamental two problems, either that the legal standard that Dr. Wall was endeavoring to apply was wrong or that his understanding of it was wrong; or, and I think even more problematically, that Dr. Wall simply did not have the opportunity to do what experts are supposed to do, which is not to receive a report that has been written with evidence cited in it and sign off on it, but rather to review that evidence in the first instance and select from it those facts that are germane to the expert's opinion.

Weighing the evidence pro and con, that is the

essence of the expert task. That is what ensures at least some level of methodological rigor. That is what affords the opportunity to cross-examine an adverse witness, and that was what was not present here.

THE COURT: Thank you.

MS. DURIE: Thank you.

THE COURT: Please.

MS. MULLIN: Thank you, Your Honor.

Defendants' motion here was made under *Daubert*, and what *Daubert* really talks about is the requirement that expert testimony is reliable and relevant. And the reliability is established when the expert's testimony relates to scientific knowledge. And defendants have not challenged the scientific validity of Dr. Wall's opinions.

He has given opinions about the substance of what Axel discloses. He has given opinions about the substance of what the other prior art references disclose; Rice, Oy, Ochi. He's given a description of the --

(Interruption by reporter.)

MS. MULLIN: He has given a description of the prior art references.

MS. DURIE: He's given an opinion of the substance of the --

THE COURT: And then you were on Ochi.

MS. MULLIN: Okay. Do you want me to try again?

THE COURT: Yes.

MS. MULLIN: So when you look up at the scientific substance of Dr. Wall's opinions, what underlies opinions on anticipation, what underlies opinions on obviousness or obviousness-type double-patenting on written description and on noninfringement, the scientific substance of Dr. Wall's opinions about what each of those references discloses about how that compares to the claims that are issued here, viewed in the context of the Court's claim construction order, is given an analysis of the written description or lack thereof in the Cabilly patent for the use of genomic DNA in the claim -- in the asserted claims here. And he's given opinions on noninfringement. And the scientific substance of those opinions has not been challenged by defendants.

THE COURT: Well, he's qualified, all right. There's no doubt about that. He's qualified to give opinions.

The problem was -- is the opinion -- does the opinion have to take into consideration the other -- any contrary facts that are in the file history. This file history is replete with argument, views that later on change. It's a very unusual --

MS. MULLIN: That's right.

THE COURT: -- file history.

MS. MULLIN: And if there's something in the file

history or if there's something in the deposition testimony that somehow undermines or contradicts what Dr. Wall says, that's appropriately the subject of cross-examination.

They are free to point to the 40 or 50 or whatever boxes of documents it is that includes the file history and say, Dr. Wall, when you said that Axel discloses X, did you know that at page 9,957 of the reexam file history the Patent and Trademark Office said why. But that's cross-examination. That's not a basis for precluding an expert from giving opinion testimony.

THE COURT: Well, here's the point. At the deposition you're getting ready to do that at a trial. In other words, the deposition, one of the reasons you take it is you want to see what the witness will answer when you put that to them. And he couldn't answer because he hadn't read the file history. And what you're saying is, so ask him that in the presence of the jury and you can read the answer.

MS. MULLIN: That's right.

THE COURT: But by that time, you'll be ready, and you don't know what his answer will be.

MS. MULLIN: Well, I don't know how ready anybody can be with 40 or whatever boxes of documents on these issues, but I also don't know how relevant they are to the -- as you note in their papers, they don't say, Look,

here's something in the file history that proves that what Dr. Wall said is so scientifically flawed that no reasonable jury could return a verdict in his favor, or here's something in the reexamination record or the interference that proves that Dr. Wall's opinion is totally without merit.

Even on the issue of written description, when they say, Oh, he hasn't looked at the entire file history, if there's something in the file history that contradicts his opinions, they can point it out to him, and they can go back to his deposition and say, And when we asked you this question at your deposition, you said you hadn't considered that, and the jury can consider that as one of the facts in weighing the credibility of Dr. Wall's opinions.

But that's not a basis for precluding him from testifying when his opinions are scientifically reliable and would be helpful to a jury.

THE COURT: Now, could I ask you what I do about the infringement testimony?

MS. MULLIN: Well, there was a claim construction for the "produced as separate molecules" element.

THE COURT: Yes, right.

MS. MULLIN: The Court said give it its plain meaning, and that's what he did. So I'm not sure the basis for precluding him from testifying based on following the

Court's instruction.

Obviously, if the Court issues some subsequent claim construction ruling that changes its earlier opinion, then we may ask for leave to --

THE COURT: We'll get -- we'll get to that.

I take your point. No reason to exclude him. Yes.

MS. MULLIN: And a lot of this seems to be that there were -- there were questions at the deposition that were phrased in a way that fell within this stipulated provision in the protective order that protects certain communications and drafts, et cetera, with expert reports.

But what they never asked Dr. Wall, and what they're asking the Court to infer a negative answer to, is the question: Are these your opinions? Did you review Axel? Did you understand what was going on in the field at the time? Is this opinion based on your scientific knowledge?

They never asked him that question -- or those questions, and now they want the Court to infer that the answer to those is no and not allow him to testify at all. I would welcome them to ask Dr. Wall on the stand if they're his opinions.

Let me address a few of the other points. On the issue of obviousness-type double-patenting, we can look at

Dr. Wall's report where he clearly talks about the claims of the '567 patent.

THE COURT: I did. I looked at them.

MS. MULLIN: He does the comparison. I understand, you know, during his deposition he was asked, Is there a difference between obviousness-type double-patenting and obviousness, and he said, Yes. I'm not actually quite sure what the issue is here. He did use the Cabilly I patent claims as a baseline for --

THE COURT: Well, he technically -- this is a question of legal definition, and he did, in the Court's opinion, not have the right definition in mind. That's all I can say about it.

MS. MULLIN: What will happen at trial is he can give -- he can say, Here's what the Cabilly I claims say, here's what the Cabilly II claims say, here's my opinion as to why they're not patentably distinct. The Court is going to instruct the jury on the law anyway. I can't imagine Mr. --

THE COURT: In this particular instance, this is a very tough question, the issue he was dealing with.

MS. MULLIN: It is a tough legal question, you're right.

THE COURT: Tough, tough issue.

MS. MULLIN: And he was not very facile in

explaining the law.

THE COURT: No.

MS. MULLIN: But he's not going to be explaining the law to the jury. He can give, Here's what Cabilly I claims are. Here's my opinion as to whether or not they're patentably distinct from the Cabilly II asserted patent claims here. The Court is going to instruct on the law anyway, and then the jury can go back, and they -- they're ultimately going to decide anyway for all of these issues whether the scientific basis for his opinion matches the opinion in view of the law that the Court instructs.

On the issue of written description, he did have the law correct there. He was asked, Do you have to have an example to satisfy the written description requirement, and he said, No. He was asked, Does there have to be an actual reduction to practice, and he said, No.

But then he was asked, So what kinds of things would be good evidence of the applicant's having possession of the invention, and he gave some explanations as to that. That's different than saying he misunderstood the law.

And, again, if they want to cross-examine him about -- bless you -- about the bases for his opinions, they're free to do so, and the Court will instruct on the law, and the jury can sort it all out.

The same issue on written description where they

say, He didn't look at the entire record of this deposition testimony. I mean, there's a voluminous record in this case. But they haven't pointed to anything in the deposition testimony that he didn't consider that would undermine the scientific reliability of his opinions. And if they want to do that, again, during trial, they can do it. They can cross-examine him on that subject matter.

Finally, I think there was an issue with respect to the way the PTO made certain determinations about Axel. There seems to be an argument that Dr. Wall should not be able to testify about Axel anticipating -- I guess it's anticipating the claims here because the PTO considered Axel in the context of some other rejections in the patent office during the reexam. Well, that -- of course, Dr. Wall is free to disagree with the PTO.

We wouldn't have district courts and juries considering validity after a patent issued if experts were not free to disregard -- or disagree with the examiner's assessment of what was disclosed by a prior art reference or how it applied.

Particular statements at issue here that Dr. Wall made were that there were no arguments about anticipation made during the reexam proceeding. Defendants have conceded that's true. They're now arguing that his opinion should nonetheless be disregarded because somehow he should have

known that the PTO has some regulation in 37 CFR that talks about completely considering all bases of patentability and he didn't know about that. And, again, if that's really critical to his opinion, then they should cross-examine him on it.

But, frankly, it doesn't make what he said in his report wrong, and it doesn't undermine the scientific validity of his opinions.

So I think the one other issue is this issue about claim construction and the opinion that Dr. -- Dr. Wall gave in his opening report, which would have been the report where he talked about issues on which we have the burden of proof, was that the Cabilly II patent does not provide a written description for an invention where genomic DNA is used.

There is an express statement in the Cabilly specification that says that when you're making the antibodies in the present invention, that the DNA that you use is cDNA, and on that basis, if the claims are such that they encompass cDNA as well as genomic DNA, those claims are invalid because the Cabilly II specification does not provide written description for that.

Now --

THE COURT: When -- when did that enter the case?

MS. MULLIN: Well --

THE COURT: Because I've never seen that before. I know that it's in there now. I know what he said about it. I am somewhat baffled by the issue because I have not -- I understand generally how he sees it, but I've never thoroughly gotten into that.

MS. MULLIN: Well, there is a phrase in each one of the asserted claims here, DNA sequence and coding, and the question is what does that mean. And during the claim construction process early in the case, nobody brought it up, and, obviously, we hadn't appreciated that there might be an issue at that time.

THE COURT: I should say nobody brought it up.

MS. MULLIN: I know. But we recognize now that Dr. Wall, having given his opinion -- that there's a lack of written description for genomic DNA, and that some of this might revolve around the construction of that phrase, DNA sequence and coding; that either the defendants could ask or the Court could decide that it's appropriate to have claim construction of that term now.

And so in the event that's going to happen, Dr. Wall did provide some information in his report that might be helpful to the Court.

THE COURT: It -- if it had come up sooner, if the Court had been given an opportunity to look at this issue, I might be able to tell you how I feel about it. It's just

actually right out of the blue. I have not seen that argument before, and I thought I really had seen every argument that could be made about it in one way or another; not necessarily in this case, but I've seen almost all the arguments, and I have read the file history on more than one occasion, and I've never seen this issue.

MS. MULLIN: And, actually, that's one of the reasons why Dr. Wall provided it in his report, an explanation that maybe isn't so apparent to me, but when you understand the science and understand what the Cabilly applicants were arguing to distinguish over prior art references, you understand that one of the ways they were distinguishing their invention was by saying, Look, prior art used genomic DNA. We used cDNA. And that was some of the basis for some of their arguments during prosecution.

THE COURT: You may believe me when I reiterate to you that I didn't think there was something that I had missed in Cabilly. I don't believe that I have seen this argument before. I don't know what to do with it.

MS. MULLIN: Well, the issue of claim construction can be one that's resolved later, but regardless of how that is resolved, there's no basis for precluding Dr. Wall from testifying that what the Cabilly specification says is that the present invention is made using cDNA. That's what it says. And when he reads that as someone who's skilled in

the art, he does not believe that the Cabilly applicants have conveyed that they were in possession of an invention that utilized genomic DNA. And it really makes sense, because the Cabilly specifications talk about using E.coli, and you can't use genomic DNA in E.coli.

THE COURT: So he says.

MS. MULLIN: So that opinion stands alone and is completely separate from --

THE COURT: I'll say it's -- I should say it does.

I don't know what to say about this right at the moment. I've said everything I can say. I have been puzzling over it. That is the one thing that I particularly wanted to deal with.

Fine. Is there anything else?

MS. MULLIN: No. I'll just close by saying if Dr. Wall's opinions were so scientifically flawed, we would be here defending against a number of summary judgment motions, but we're not because it's not the scientific substance of Dr. Wall's opinions that are being challenged. They're reliable and they're relevant, and therefore under *Daubert* and the factors articulated by the Ninth Circuit, they're admissible.

THE COURT: All right. Now, I just want to ask you, please, to comment on the last thing that we were talking about because I was -- I was reading along, and

there is something that hasn't come up before.

MS. DURIE: The Court is correct. That is not something that has come up before.

THE COURT: Now, I mean in other cases even.

MS. DURIE: Correct. This is an entirely new issue that was raised in this case well after the claim construction process.

THE COURT: That's quite so.

MS. DURIE: In which Dr. Wall offers the opinion that the term "DNA sequence" would be understood to be limited to cDNA and that it would not encompass genomic DNA.

THE COURT: That's right.

MS. DURIE: Notwithstanding that there is no such limitation in the claims of the patent.

THE COURT: No, there isn't.

MS. DURIE: Notwithstanding that there is a discussion in the specification of the patent relating to practicing the invention in mammalian cells. Notwithstanding that our expert has proffered an opinion that in reading the specification and the discussion of mammalian host cells, there are references that a person of skill in the art would understand to be references to genomic DNA.

Now, of course, Dr. Wall has not read that, and so, therefore, could not be examined about it. This is --

this is a new issue. He brings it both as a claim construction issue and as a written description issue.

THE COURT: Yes.

MS. DURIE: But in neither case has he done the work that would be required for him to render a competent opinion because both claim construction and an evaluation of the written description issue would require Dr. Wall to have read the record.

For purposes of written description, here is where he is relying on testimony from Art Riggs, admitting that he has not read that testimony in context. That is where he is relying purportedly on the testimony of one of the inventors whose deposition apparently he hadn't read at all.

The -- what *Daubert* -- *Daubert* is not simply directed to whether an expert's opinions are couched in terms of science. There are three requirements for *Daubert*: 7021, the expert must identify and assemble the relevant facts; 7022, the expert must understand the applicable legal principles; and 7023, the expert must apply those principles and appropriate scientific methods reliably to the facts of this case.

The problem here is not whether the substance of Dr. Wall's testimony is directed to issues of science. The problem is that there is no scientifically reliable methodology underlying his opinions, and that is equally

true with respect to his opinions directed to genomic DNA.

And it is not a sufficient answer to say that Dr. Wall can be cross-examined on the universe of things that he failed to consider in front of the jury because *Daubert* places responsibility in the courts to exercise the gatekeeping function and ensure that testimony that lacks methodological rigor, where the expert has not worked in the same way that he works in the field in order to present opinions to the jury, and there is no universe in which the normal way that a scientist such as Dr. Wall formulates opinions is to rely on excerpts of records selected by counsel.

That's why in the *Rockwell* case the Court did not undertake any inquiry into whether the expert's opinions were correct, whether they were scientifically valid, whether he had made mistakes in -- in analyzing the significance of the evidence. The Court instead pointed to a much more fundamental problem which was that the expert was relying on digests of testimony prepared by counsel, and that methodological error was sort of in and of itself sufficient to exclude the expert's testimony.

That is the case here. Dr. Wall has simply failed to do the work of an independent expert with respect to each of these issues.

THE COURT: Now, we didn't have that opinion at

the time you took his deposition, did we?

MS. DURIE: *Rockwell*, I believe -- I don't remember when the Rockwell opinion came down, but there are -- if that's what the Court is referring to, but there are a number of opinions that are along the same lines and that make clear that the -- the task is not -- the task here -- the predicate task here is to assess whether the expert has selected the facts, analyzed some universe of evidence, and made decisions with respect to what evidence does and does not support the expert's position.

And here, it is not simply the case that Dr. Wall made decisions that certain pieces of evidence were not germane to his analysis and could be cross-examined about that; he is ignorant.

Counsel's correct. It would be very difficult to cross-examine Dr. Wall with respect to the 40 pages -- 40 boxes of the reexamination record and associated file history if he hasn't read any of it and, therefore, to elicit from him any intelligent opinions as to the significance of that evidence, and that's why the courts require experts to engage in the work of an expert themselves and not simply to recite opinions based upon evidence, all of which has been generated by counsel.

THE COURT: Thank you.

MS. DURIE: Thank you.

THE COURT: All right. Now let's go on to no willfulness.

MS. MULLIN: Your Honor, if I may make just one or two comments?

THE COURT: Yes.

MS. MULLIN: Written description is assessed based on the four corners of the specification, period. That's the law. All this argument about, you know, Dr. Wall should be precluded from giving testimony about his written description opinion because he didn't consider 40 boxes of reexamination prosecution history is a complete red herring. Written description is reading the specification to someone skilled in the art, appreciate that it conveys that the applicants possess the invention.

THE COURT: Thank you.

MS. MULLIN: Thank you.

THE COURT: Now let's go on. And you've got four motions here, and you can address them all at the same time, if you want to, or you can do whatever you like.

MR. MASLOWSKI: Your Honor, I think I will just address the first one.

Your Honor, we've prepared a slide presentation for all of our motions, and we've also printed out the slides, so with your permission, I'll hand up a couple of copies.

THE COURT: Certainly.

MR. MASLOWSKI: Good morning, Your Honor. I'll be addressing, as I mentioned, Centocor motion number one.

Centocor has moved for summary judgment of no willful infringement. And with your indulgence, I'll just take two minutes to kind of set the stage for this motion.

The *Seagate* test out of the federal circuit was a two-prong test for willful infringement. Just generally, the first prong of the test is an objective analysis, and the second part is a subjective analysis.

THE COURT: I know.

MR. MASLOWSKI: Our motion focuses solely on the objective portion. There are three tidbits of law that are primarily relevant to our motion.

The first is the state of mind of Centocor is completely irrelevant to Centocor's motion, as is any evidence related to the issue. The second point is the reexamination of the PTO is a factor that may weigh against a finding of objective recklessness. And the third point is that legitimate defenses to infringement and credible invalidity arguments also weigh against objective recklessness.

THE COURT: What's the time period we're looking at here now?

MR. MASLOWSKI: Very good question, Your Honor.

I'll go to my slide here that I created as a timeline.

THE COURT: Oh, yes.

MR. MASLOWSKI: I will say for the record that I did do this all by myself.

So the time period that we're focusing on, really, for purposes of willfulness, is the first point of infringement which would be Remicade in October of 2008.

Obviously, we have to look a little bit back in time. So working left to right on the timeline, the PTO granted the reexamination in July of 2005, and then critically -- the critical point to this motion is Centocor filed a lawsuit in May of 2008 where it, as plaintiff, asserted claims seeking to invalidate the Cabilly II patent, seeking to have it declared unenforceable and also seeking a finding of noninfringement.

After that time period, as the reexamination continued, Centocor terminated its license to Celltech, and in October of 2008, the first alleged Remicade infringement occurred.

Shortly after that time frame -- I shouldn't say "shortly after that time frame." Months after that time frame, the PTO issued its notice of intent to issue the reexamination certificate. Then after that time frame, Simponi, another accused product in this case, launched, and then a month or so after that, the reexamination certificate

issued from the PTO officially ending the reexamination.

Now, defendants make a -- or attempt to make a big -- or make an argument about that, that the termination of the reexamination should be dispositive in their favor. That ignores one big factor. That factor is that by the time the reexamination had terminated, we were months and months and months into this lawsuit, and the law says that credible invalidity and noninfringement arguments is evidence of lack of objective recklessness.

So by the time the reexamination terminated in May of 2009, it said, We are a year into this lawsuit, and, has just been discussed, for example, in the last motion, it's clear that Centocor has credible invalidity arguments, for example, with respect to the written description issue.

So after the reexamination certificate issues, Stelara, another accused product, launches and brings us forward to today.

So to touch on a couple of points that defendants made in their motion, again, the Centocor-Celltech license is completely irrelevant to this motion. The law is clear that Centocor's subjective state of mind has no bearing on the objective prong, and that's where their arguments are directed at; that somehow Centocor's subjective state of mind with respect to its termination, the valid termination, of that license is somehow evidence of objective

recklessness.

That is in fact not true. Centocor is entirely permitted to terminate that license. And even if wasn't, even if there was the chicanery the defendants seemed to have drummed up in their opposition motion, the bottom line is, it is totally irrelevant to this motion. This motion focuses on the objective prong. So Centocor's subjective state of mind has no bearing whatsoever.

In addition, defendants allege that somehow our continued payment under the ReaPro license, another Cabilly license for the product ReaPro sells, is also somehow evidence of objective recklessness. Again, two points, the first being the most important: Centocor's subjective state of mind with respect to what it is doing with respect to its ReaPro license is totally irrelevant to the objective prong; the second point is it makes complete business sense for Centocor to continue to pay on its ReaPro license.

As this Court will recall, there was extensive briefing and a summary judgment hearing on the covenant not to sue that's contained in that ReaPro license. The Court determined that at least as far as Centocor Ortho Biotech, Inc., in the product Remicade, Centocor Ortho Biotech, Inc., has a covenant not to sue from defendants for that product.

Obviously, if Centocor were to terminate the ReaPro license, defendants would allege that that covenant

was extinguished as well. So it makes perfect sense for Centocor to continue to pay for the ReaPro license.

Again, going back to the primary point, whatever Centocor is doing with respect to its ReaPro license is irrelevant to the objective prong.

So, in sum, the defendants make -- or attempt to make points about the -- about Centocor's defenses and say that they lack merit; that, for example, Dr. Wall, which we've already been through -- that somehow Dr. Wall's opinions show that Centocor does not have credible and legitimate defenses in this case, but, as my colleague, Ms. Mullin, said, it's interesting that defendants have filed no summary judgment motions on their own.

If our defenses -- our noninfringement defenses, if our invalidity defenses, our enforceability defenses were as weak as they might suggest, it's likely we would have seen summary judgment motions in some fashion from them, but we have not.

It's also important to note that we don't have to prove that our defenses would win. The law is clear that they just need to be legitimate defenses. They need to be close calls. We do not have to show for our motion that we would actually prevail.

So, as I mentioned previously, it seems as if the written description motion is certainly, at a minimum, a

close call, although Centocor suggests that it's obviously in their favor, but at a minimum, I think all parties will agree that it's a close call. So that alone is a sufficient defense, a credible defense, that supports a lack of objective recklessness.

And again, just briefly, a point made in our briefing relates to the claim construction arguments. We had claim construction arguments that we set forth but failed. If those claim construction arguments would have prevailed, we would have had additional noninfringement positions. That evidence, too, weighs in favor of a lack of objective recklessness.

In sum, the two primary events that we focus on in our brief and in our motion are the reexamination proceeding and our credible and legitimate defenses.

And I should point out that it seems that defendants do not dispute that at least up until the time of the conclusion of the reexamination, there can be no objective recklessness. They don't seem to counter that point in their brief at all. So at a minimum, up until May of 2009, there can be no objective recklessness.

Their brief, however, as I mentioned, fails to acknowledge that our lawsuit at that time was pending, and we had our legitimate defenses in place such that our motion should be granted not only until up until the end of the

reexamination period but through the entire case.

My last point that I will raise relates to defendants' allegations in their opposition brief that somehow there are documents out there that have not been produced related to this issue. Again, as with all their other arguments, the documents that they're complaining about relate to Centocor's state of mind with respect to its Celltech license. Again, that issue is completely irrelevant to their motion.

The second point is, we've produced everything that they've asked for. There was testimony in April of this year where a Centocor witness indicated that Centocor stopped paying its Celltech royalties because they believed the patent was invalid. Lawyers for the defendants sent a letter to Centocor and said, Your witness just waived on the issue of validity of the patent, the Cabilly II patent. We want all documents on that issue. We said okay, and we produced those documents.

It was at that time, after we agreed to produce those documents, that they then sought to broaden the scope well beyond just the validity of the Cabilly II patents. They wanted all --

THE COURT: I'm not sure I understand the point you're making.

MR. MASLOWSKI: I'm countering their argument that

somehow they say that there are documents that need to be produced that are relevant to this issue.

THE COURT: Oh, I see.

MR. MASLOWSKI: The first point is, they're just not relevant to the disposition of this motion. The second thing -- the second point I'll just make in closing, is all the documents have been produced.

THE COURT: Now, how are we going to proceed? Are you going to oppose this right now?

MR. LIPNER: Whatever Your Honor wishes. I would be happy to address these arguments.

THE COURT: Please.

MR. LIPNER: Joseph Lipner of Irell & Manella for City of Hope, Your Honor.

THE COURT: Yes. Good morning.

MR. LIPNER: Good morning.

May I ask for -- may I place slide 6 from Centocor --

MR. MASLOWSKI: Just the back arrow.

MR. LIPNER: Just the back arrow? Page up?

THE COURT: Slide 6.

MR. LIPNER: Your Honor started with a very pertinent question to counsel for Centocor, and that is, what time period are we talking about in connection with the claim of willfulness in this case. We have in -- under the

facts in this record some classic willfulness facts which, in our view, not only overcome the request for summary judgment but make this a particularly compelling case for a finding of willfulness, and that can be seen from the very timeline of events in this case.

There is no question that in February of 2009 the patent office, as Your Honor is well aware, issued its notice of intent to issue the reexamination certificate, and we have testimony from Centocor's chief executive officer and designee on willfulness issues, Robert Baysmore (ph), that notwithstanding the issuance of the NIRC, Centocor took no other action to ensure that it was respecting Genentech and City of Hope's patent rights.

Mr. Baysmore also testified, in his capacity as designee for Centocor, that it was Centocor's hope and position that the reexamination would be successful in invalidating the Cabilly patent and that that would be the basis for not paying royalties further on the Cabilly patent.

Notwithstanding that hope, notwithstanding the testimony of Mr. Baysmore, that Centocor was following the reexamination closely, Centocor didn't do any further due diligence after the time that the NIRC issued.

And if we look at the timeline provided by Centocor, you can see that the first Remicade infringement

took place only a few months before the NIRC issues in October of 2008, a matter of three or four months before the NIRC issues, and Simponi, another accused product in this case, launched several months after the NIRC issued in April of 2009, and Stelara launched yet a number of months after that.

So at a time when the patent office had issued its NIRC and, in the case of Stelara, at a time after the patent office had reaffirmed the validity of the Cabilly patent, Centocor was nevertheless proceeding with its plan to infringe with respect to Remicade and was beginning its infringement with respect to both Simponi and Stelara.

Now, cases, such as the *Ultra Tech* case out of the Middle District of Florida and the -- the *Palm* and *Matsushita* cases out of the District of Delaware where the plaintiff was *St. Clair* in both cases, have held that a decision to continue with infringement after the time the reexamination ends appropriately with a finding that the patent is valid can be considered objectively reckless under the first prong of the *Seagate* test.

So we have that basic fact of the end of the PTO reexamination and Centocor's failure to do any due diligence and its proceeding with its firm plan to infringe patents with respect to Remicade, Stelara, and Simponi. All of the other facts, some of which are eyebrow raising,

really relate to this issue of Centocor's failed gamble that the PTO would relieve them of the obligation to pay royalties.

Mr. Baysmore's testimony makes clear that that is exactly what Centocor was doing. And so when Centocor works for four months with Celltech to unwind the license agreement in a way that rewrites the entire relationship between Centocor and Celltech, with one notable exception, and that is that it cuts Genentech out of receiving any royalties and ends the license to the Cabilly patent, that is part of this gamble taking place as it did during the time when the claim stood rejected in the patent office.

Same thing with Centocor's explanation of its claim -- of its continued payment on ReaPro. Centocor says that it wants to keep the benefits of section 2.02 of the ReaPro agreement, which Your Honor has studied very carefully, a limited agreement not to sue Centocor in connection with certain product -- a certain product.

Centocor's explanation, given for the first time in its reply brief, is that it wants to keep the benefits of that as a, quote/unquote, insurance policy in case its gamble doesn't pay off. It has nothing to do with whether they're infringing or not infringing a valid patent. It's all part of this gamble to try to stop paying royalties, notwithstanding what the patent office said, notwithstanding

what happened in the reexamination.

And Centocor is a sophisticated company. It took that gamble with its eyes wide open. It thought it would enure to Centocor's benefit, and when it didn't and the Centocor plan did not work out and the patent office reaffirmed the validity of the Cabilly patent, Centocor should have to bear the consequences, and that is to defend against a claim of willfulness because it leaves them somewhat naked in connection with this matter.

Now, Centocor has also addressed the issue of its defenses in this litigation.

THE COURT: Yes, right.

MR. LIPNER: So there are a number of things that need to be discussed about this. Unfortunately for Your Honor, the *Seagate* -- application of the *Seagate* test is still developing through the court system.

THE COURT: Don't worry about it. That's what lots of patent law is presently developing.

MR. LIPNER: Absolutely, Your Honor.

And *Seagate* itself stated that -- when it announced its new standard, that they announced a broad standard, and they left it to courts to decide how to apply the standard in a case-by-case basis. As Your Honor stated, *Seagate* said, The Federal Circuit said we leave it to future cases to further develop the application of the standard.

And, as Your Honor said, district courts, like Your Honor, are very well-versed in figuring out how to do that step by step.

Let me talk about what's clear under the law, under *Seagate*, about Centocor's defenses and then where there's a conflict in the law currently. What's clear is that it is definitely not enough for Centocor to simply have defenses to Genentech and City of Hope's claims for infringement, defenses that they could present at trial and make an argument.

There is no question that the defenses, in order to provide them to a -- provide them with a defense to willfulness, must be a close question that gives the Court, and perhaps the jury, some pause about which way it should come out.

The Federal Circuit in the *i4i Limited Partnership* case said -- Microsoft was the accused infringer there, and it said the fact that the Microsoft presented several defenses at trial, including noninfringement and invalidity, does not mean that the jury's willfulness finding lacks a sufficient basis.

A nice example of this can be seen from the *Safoco* case that is briefed by both Centocor and City of Hope and Genentech, out of Texas. And in *Safoco* there were two patents at issue. With one of the patents there were

clearly legitimate invalidity arguments, but the Court did not consider it a particularly close call, and, therefore, denied summary judgment of willfulness on that patent.

So the question is not merely whether defenses exist but whether they're a close call. And, quite importantly, it's not only that they be a close call as to some issues in the case, but they have to resolve the entire case in Centocor's favor.

And it's quite significant, to that end, to note that all of the summary judgment issues that we are discussing this morning brought by Centocor relate only to claim 33 and not to claim 18 and 20. For Centocor to make this close-call argument, it would have to convince the Court that it had close arguments on all of the asserted claims in the case, and we don't believe it has done that.

Indeed, I hope we've demonstrated to Your Honor through our briefing and through the further arguments that you'll hear this morning that we do not consider the arguments raised by Centocor to be the kind of close call that the courts are talking about post *Seagate* that provide a defense to willfulness.

Now, before I leave this issue of defenses and what their effect is on the willfulness analysis, I do want to bring to Your Honor's attention where the law is currently unclear.

Centocor is making an argument as though the existence of a close question in the abstract, just floating out there, by the time they get to trial in and of itself defeats a claim of willfulness. Well, there are different analyses in the courts about this important issue.

And so there are cases such as the district court decision in the *i4i Limited Partnership* case, which was later affirmed by the Federal Circuit, which say that is not the test at all. To quote from *i4i Limited*, they stated, As a consequence, the number of creative defenses that Microsoft is able to muster in an infringement action after years of litigation and substantial discovery is irrelevant to the objective prong of the *Seagate* test. Rather the correct analysis focuses on whether, given the facts and circumstances prior to Microsoft's infringing actions, a reasonable person would have appreciated a high likelihood that acting would infringe a valid patent.

And another case that held similarly, that you look at what arguments were available not at the time of trial but at the time of first infringement and at each relevant stage thereafter, is the case called *Krippelz*, K-R-I-P-P-E-L-Z, out of the Northern District of Illinois. They do the analysis exactly the same way.

In fairness, Your Honor, there are cases that support Centocor's view that you don't look at it in a

time-bound way. There's the case that they rely upon. I think it's called *Hepscomb* (ph) out of Michigan. And that disagreed with the two cases that I mentioned, although *Hepscomb*, if I'm saying the case correctly, came out criticizing the *i4i* district court decision before it was affirmed by the federal circuit this year.

So, Your Honor, under that analysis you don't even get to the question of looking at what Centocor's current defenses are. But they have to make a demonstration of what the defenses were that were allegedly close questions at the time they began infringing. And you can look, Your Honor, at their interrogatory responses, which are Exhibit QQ to the Pals's declaration, in which they gave the state of their thinking back in April of 2009 where the arguments presented are quite sketchy and skimpy, except to the extent that they parrot the reexamination arguments on which they were gambling.

So that's the state of the law on this close question. There's some ambiguity in the law. But even if the Court is going to consider it, it has to be a close question that causes substantial doubt, and it has to relate to all of the claims in the case.

Finally, we get to the issue that caused Your Honor to -- Your Honor's last question about what is going on with the documents relating to willfulness. And the

bottom line is, we are defending this particular motion at a time when Centocor has not finished its relevant document production that relates to a claim of willfulness, and, that is, Centocor has produced a handful of previously privileged documents during the course of the parties' meet and confer, but there are three things that remain open with respect to the document production.

First of all, as Your Honor will see, if you look at Exhibit M to the Pals's declaration, for months we've been asking Centocor as to whether they have completed their further search for all documents that they intend to produce. Even in the reply brief we haven't gotten an answer that that search is complete.

Second of all, we've asked Centocor for the answer to the simple question about whether they are waiving privilege because they are relying on advice of counsel. They've provided some deposition testimony that's about discussions with counsel. They've provided a handful of documents. But when we've asked them, Are you waiving privilege in order to rely on advice of counsel, they have refused to answer, saying, It's not ripe yet. So we don't know the answer to that fundamental question.

And, finally, and most substantively, Centocor appears to be producing, apparently to defend against a claim of willfulness, only documents that touch on the

question of the validity of the Cabilly patent. Their designee and chief financial officer, Joseph Woke (ph), testified that that was the reason they stopped paying on Remicade. We've asked them to produce other previously priveledged documents that would allow us to test that proposition, and so far they've refused.

They haven't produced any previously privileged documents that show other reasons for failing to pay royalty on Remicade, nor have they said that they would produce those documents. They've only selected the previously privileged documents that they want to produce using the privilege as a sword and not a shield -- as a sword and a shield at the same time.

And so in defend -- it's relevant to this motion and it should not be lost that we are defending this on an incomplete record, they argue that it -- those relate to the second prong of the *Seagate* test. They certainly relate to the second prong of the *Seagate* test. But what the cases clearly show is that when you look at objective recklessness, you have to look at it in light of the facts and circumstances surrounding the infringer's infringement. And so those documents would be relevant to that issue, as well.

Thank you, Your Honor.

THE COURT: Please.

MR. MASLOWSKI: Just a couple of quick points, Your Honor.

First, with respect to -- on the timeline, the issuance of what they're referring to as the NIRC, they're indicating that we should have done something else. Centocor should have taken additional steps. That ignores the fact that we already took additional steps. We're already in the middle of a lawsuit that we had filed many months before where we asserted defenses of invalidity, unenforceability, and noninfringement.

I'm not sure what else we were supposed to do other than continuing our lawsuit where in fact we're asserting defenses that -- some of which which had not been considered by the patent office.

Second, with respect to the state of the law, the following is a quote from *Seagate*: A substantial question about invalidity or infringement is likely sufficient not only to avoid a preliminary injunction but also a charge of willfulness based on post-filing conduct. I'm not sure it can be any more clear than that, Your Honor. That's the law.

The law is, if there is a substantial question about invalidity or infringement, that weighs in favor of non-willfulness. That's the basis of our motion. There can be no dispute about that law.

Third, with respect to the fact that we're only here today to argue about claims or motions related to claims or just claim 33, that also ignores, one, that we did file motions related to claims 18 and 20, and it also ignores the point that I attempted to make in my opening argument which is our claim construction positions with respect to claims 18 and 20, which were that the Medimmune claim construction -- or rulings from Your Honor should have been adopted, that would have given us a noninfringement argument for claims 18 and 20.

If you recall, Your Honor made a change to the Medimmune ruling which prevented Centocor from having additional noninfringement argument. That claim construction argument that Centocor made in this case, which was adopted by Your Honor in the Medimmune case, obviously is a close noninfringement position or a close noninfringement argument. It's a reasonable position. Your Honor adopted that position in the last case but changed it here.

The only argument that defendants could raise in opposition to that point, which we made in our opening brief, was that we hadn't spelled out the noninfringement argument. That's not true. The evidence we cited to in our opening brief provided how under Your Honor's previous claim construction position we didn't infringe.

And then, lastly, with respect to the documents and the issues related to whether or not they relate to the objective prong, the bottom line is, defendants could have made a motion to compel. They didn't. They've known for months that we did not view the waiver as broadly as they viewed it. They could have made a motion months ago. They didn't.

In fact, they make a weak attempt with respect to Rule 56(f), I believe, in this case to try to prevent the grant of summary judgment, but there's no 56(f) declaration with its motion. They haven't followed the rule with respect to Rule 56(f).

So the entire red herring argument should be ignored, and Centocor's motion should be granted.

THE COURT: Thank you.

MR. MASLOWSKI: Thank you.

THE COURT: Let's go on to the next one.

MS. ELDERKIN: Good morning, Your Honor. Dianne Elderkin for Centocor, and I'm going to talk, briefly, I hope, since we're using up our time --

THE COURT: No, no. You are not using up your time. Let's get it over -- you know that I am accustomed to Cabilly and all the arguments that can be made about it, and so go ahead.

MS. ELDERKIN: Okay. I appreciate that, Your

Honor.

What I'm going to talk about is our renewed request that the Court construe the claim term immunoglobulin --

THE COURT: Yes.

MS. ELDERKIN: -- and immunoglobulin molecule. So I'm going to talk about how the patent office arrived at its construction, why it's wrong, and why it's important for us to have the Court's construction before we go to trial.

As you'll recall, as you know, as you've heard several times this morning already, the claims were under rejection at the patent office in the reexam for many years. It got to the point where Genentech -- and I'll use that term collectively for Genentech and City of Hope -- Genentech had filed its appeal brief to the board of appeals at the patent office because the claims were under final rejection.

After several months after the appeal brief was filed, Genentech's counsel handling the reexam got a call from the examiner who said, We'd like to have a interview. Will you come in.

They came in. There's an interview. And one of the few things that counsel could recall was discussed at that interview was the meaning of the term "immunoglobulin molecule" in claim 33.

THE COURT: Who said this?

MS. ELDERKIN: Genentech's counsel who was handling the reexam.

THE COURT: What's his name?

MS. ELDERKIN: Mr. Kushan, K-U-S-H-A-N.

THE COURT: Yes.

MS. ELDERKIN: And Mr. Kushan remembers the examiner asking, Would it be fair to construe "immunoglobulin molecule" as molecules that bind to antigen. The examiner asked that. He claimed that he said, Yes, we think that would be reasonable.

The interview ended. There probably was more discussed. We don't have much record of it.

The next thing that happened was the examiner, as he's required by the rules, issued an interview summary that had three sentences. And I've reproduced those three sentences on this slide, slide 10.

So the things that the examiner thought were important enough from that interview to put into the three-sentence summary are on this slide, and, as you can see, the examiner said, Discussed the term immunoglobulin molecule in claims 1 and 33. Based on the prosecution history, declarations presented in the present case, and interference record of the present Cabilly patent, the immunoglobulin molecule is considered to be an

immunoglogically functional immunoglobulin molecule.

THE COURT: I just looked at that yesterday.

MS. ELDERKIN: And the last sentence there has to do with another claim and isn't relevant to this motion.

But, clearly, the examiner came out of that interview thinking that was an important point. Not long after that the NIRC is issued, and in the NIRC the examiner says -- and it's not on this slide, but the examiner says that "immunoglobulin molecule" means a molecule that is immunologically functional and binds to a known antigen. That is on the first page of the comments in the NIRC.

The examiner then went on to explain some of the prior art. And then in his statements for patentability -- so in the summary at the end of the NIRC, when he's giving his reasons for why he's going to now say that these claims have been rejected for so long are all of a sudden patentable, he again refers to the fact that the immunoglobulin molecule is immunologically functional.

And, again, that's on this slide here, taken right from the NIRC. He says that the combination of the Cabilly I patent claims and the teaching of all these prior art references do not suggest or contain an enabling disclosure of a method to produce an immunologically functional immunoglobulin molecule.

So, in our view, it could not be clearer that it

was important to the patent office, to the examiners, that the immunoglobulin molecule that is recited in claim 33 be a functional molecule; in other words, an immunoglobulin that will bind to an antigen. That was important to them in deciding to reverse all those years of rejections and allow the patent.

Now, when we briefed this to Your Honor last year during *the Markman* proceedings, Centocor asked for a construction of "immunoglobulin" that recited that -- well, the parties agreed on the structure of "immunoglobulin," that it's a tetrameric structure with heavy chains and light chains.

But Centocor wanted a construction that also said that whether -- included in the -- in the recitation that whether or not specific immunoreactivity is a proper -- is a property. And we take that language right out of the patent. But, in essence, we asked for a construction that said the immunoglobulin molecule that is recited in claim 33 includes immunoglobulins that bind to antigen and includes those that don't bind to antigen.

Genentech at the time asked for a construction -- if it were going to be construed at all, asked for a construction that said that the molecule was capable of binding to a known antigen. I think that the construction that they would seek now is maybe a little bit different,

but I'm sure they're going to clarify that.

And why we believe the construction that Centocor requested last year and request -- that we request again is appropriate is because the term "immunoglobulin" is expressly defined in the patent specification. And the law is very clear that when an expressed definition is provided in the specification, you really need to look no farther.

You look farther, perhaps, to see if there's been an expressed disavowal, but when there is a clear definition in the patent, the cases are quite clear that that is the definition to apply. And the definition in the patent in column 1 says that immunoglobulins include both antibodies and protein substances which lack antigen specificity; in other words, which do not bind to antigens.

And the patent even says, you know, there are advantages to some of these immunoglobulins that don't bind to antigens. There are -- they can be used therapeutically. So the patent has an expressed disclosure and even says there are advantages to this one group of immunoglobulins that don't bind. So the definition is as clear as can be from the specification.

Now, if Genentech wanted to claim immunologically functional immunoglobulins, it would have been very easy to put those words in the claim. It did so in claim 9, another claim in the patent where they expressly modified

immunoglobulin molecule by calling it immunologically functional. So that would have been easy to do. They did not do that in claim 33.

If they wanted to claim only immunoglobulins that bind to a known antigen, they could have done so. They did that in claim 21 where they said that said immunoglobulin is capable of binding to a known antigen. They did not do that in claim 33.

So the plain meaning -- the plain words in the claim and the definition in the specification could not be clearer that immunoglobulin molecule encompasses immunoglobulins which bind to antigens and those which do not bind to antigens.

Now, why is that important here? It is true that it is the case that none of our noninfringement or invalidity positions, as have been presented through our experts, rely on this particular definition. I want to make that perfectly clear.

THE COURT: I know that.

MS. ELDERKIN: Okay. But it is still very important, because it's very clear to us -- now, Genentech will disagree with this, and they'll present their arguments, but there is a great body of evidence that shows that that definition was important to the patent office in reversing two and a half years of rejections of the claims.

As we've heard this morning, it is clear that Genentech intends to wrap itself in that reexamination at trial.

THE COURT: I would. Wouldn't you?

MS. ELDERKIN: I probably would, Your Honor, but I would do it cautiously, because I think it's quite clear from the record that the patent office got it wrong, and one of the reasons they got it wrong is they misled themselves on what the proper construction of the terms in the claims are.

THE COURT: They certainly worked on it long enough.

MS. ELDERKIN: They did. They did. And they got it wrong, Your Honor, which frequently happens.

We should be entitled to make that argument, and we are not going be able to make that argument if we don't have a construction from the Court on what the proper construction of immunoglobulin molecule is.

Another reason why it's relevant and why we need the construction is that Genentech has proffered evidence of alleged commercial success to rebut our obviousness arguments.

THE COURT: Could you -- could you possibly counter their commercial success?

MS. ELDERKIN: Well, certainly, in terms of the

scope of the claim, yes. Their commercial success has to do with their licensing success.

THE COURT: Of course.

MS. ELDERKIN: Of course. And while there are several things there, we all know lots of times companies will take a license to avoid litigation. It's not necessarily dealing down to the patent and how wonderful an invention it is. So there's that point to begin with.

But the second point is, if the claims are construed, as we believe they must be, in view of the definition of the specification to include not only immunologically functional antibodies such as those that have been licensed but those immunoglobulins that are not functional, then their evidence of commercial success is not commensurate in scope with the claims, and that's a real issue for whether that evidence should even be admissible or how relevant it is because the law is quite clear that commercial-success evidence has to be commensurate in scope with the claim, the scope of the claim.

So those are two reasons why we ask Your Honor to construe the term "immunoglobulin molecule." And, of course, the term "immunoglobulin," which is used in claims 18 and 20 to modify the heavy and light chain, we believe should have the same meaning. And that's what we request, Your Honor.

THE COURT: Please.

MS. DURIE: Your Honor, nothing has changed since this Court previously concluded that there was no reason to construe the term "immunoglobulin molecule" with respect to the necessity for such a construction.

The Court had appropriately determined that it would wait to see whether there was any substantive issue in the case that turns on that construction, and we now know that the answer to that question is no. Because as Centocor's counsel has admitted, not a single one of the opinions proffered by their experts on infringement or on validity hinges in any way on the answer to this question.

Centocor asks the Court to construe the term "immunoglobulin molecule" solely as part of its effort to discredit the results of the reexamination, but because Centocor has no argument for how the construction of the term "immunoglobulin molecule" could have mattered to any issue that was actually in front of the PTO in connection with the reexamination or why the faulty construction -- the supposedly faulty construction of "immunoglobulin molecule" actually would have made a difference, Centocor is simply inviting the jury to speculate, without any basis for reaching an informed decision, as to whether this made a difference.

And how -- can I go back?

THE COURT: What?

MS. DURIE: I'm sorry. I wanted to go back to slide 11 in Centocor's presentation where they pointed to the statement of reasons for patentability and/or confirmation.

But what we see here is that the patent office said that the combination of the Cabilly I claims and the teaching of these various prior art references do not suggest or contain an enabling disclosure of a method to produce an immunologically functional immunoglobulin molecule by independently expressing immunoglobulin heavy chains --

THE COURT: That is what it says.

MS. DURIE: -- and light chains in a single transformed host cell.

The underlining is that of Centocor's, not that of the Patent and Trademark Office, and there is no reason for privileging that particular phrase over any other.

It is a consequence of the way that the system is set up that the Patent and Trademark Office is a little bit of a black box, as this Court previously has recognized. We cannot know what was in the mind of each of the many people who were involved in the reexamination process.

Instead what we have is the result of the reexamination which serves, in a way, to implement the

presumption of validity and the fact that we give what amounts to administrative deference to the actions of the Patent and Trademark Office, but it is not an invitation to have sort of a second trial within a trial as to what various arguments might have been adduced with respect to the significance of this limitation and whether it might or might not have changed the analysis.

In short, Your Honor, had Centocor come forward with a reason that the term "immunologically functional" made a difference with respect to a particular invalidity argument, then we would be in a very different position, but they did not, and for that reason the Court appropriately should, once again, decline Centocor's invitation to construe this term.

Now, Centocor's other argument for why the Court should proffer a construction now has to do with the evidence of commercial success. The problem here, Your Honor, is that by its nature, evidence of commercial success is always tied to particular products that embody the invention. That is what we have in the case here. There is extensive evidence of commercial success, not merely sort of with respect to licensing in the abstract but with respect to many products that have come to market, both products made by Genentech and products made by third parties, that embody the claims of the Cabilly patent.

THE COURT: I don't think there's any question about that.

MS. DURIE: And it is, of course, always the case that evidence of commercial success pertains to evidence that some particular embodiment of the invention is successful. And the reason that that evidence is powerful evidence of nonobviousness is that the proposition is that if there were ways to be successful practicing the invention, others would have done it before.

But it cannot be the case, as Centocor proposes, that the fact that there might be some embodiments of the invention that would be less commercially successful means that it is impossible to support the nonobviousness of the invention with evidence of commercial success, and that is what we have here. We have a wide range of products embodying the invention that are commercially successful.

Now, again, I think the Court does not need to reach the issue of what is the proper construction of "immunoglobulin molecule," but were the Court to reach that question, I think it is important to note that it has to be understood in view of the unique history of this patent and the fact that we have such an extensive record going back to the fact that the claims originally did arise out of an interference where we had the Boss patent using the term "immunoglobulin molecule" and the Cabilly specification

using the term "immunoglobulin," that we then had a record arising out of that interference and the section 146 action in which, as the Patent and Trademark Office observed, the parties understood the claim term at issue here to require that the molecule be immunologically functional, and that when the Patent and Trademark Office considered this question of what was an appropriate claim construction, it was looking at that very long and extensive history.

And, of course, for this Court in making the determination of what is the proper construction, it is not simply the case that the Court substitute its judgment for that of the Patent and Trademark Office, because the PTO's determination in the reexamination is now part of the record on which this Court must base its conclusion.

We have a statement by the examiner as to what would be a reasonable construction. We have Genentech and City of Hope's acquiescence in that construction. And I think it's important to note that if Centocor were in here arguing for a broader construction of the term, it would be very hard indeed for Genentech and City of Hope to argue against that.

And yet the proper claim construction does not turn on the party advancing the argument, precisely because it is a question of law. Does not matter which side is arguing for which construction.

And -- and I would simply submit that if we were here asking the Court that the construction of the term "immunoglobulin molecule" should include nonspecific immunoglobulins or immunoglobulins that do not demonstrate functional binding, that would be, in light of the extensive prosecution history in this case, an untenable position.

THE COURT: All right.

MS. DURIE: Thank you.

THE COURT: Now, I've given a great deal of thought to this next one, so you go ahead. This is on claim 33. Yes?

MS. ELDERKIN: Yes, Your Honor.

Centocor's motion No. 3 seeks summary judgment of no infringement of that claim based on the "produced as separate molecules" language. And I'd like to explain why under the plain meaning of that language, which is what the Court has twice said, applies, Genentech simply cannot meet its burden of proving infringement.

Again, the language in claim 33 talks about the immunoglobulin heavy and light chains being produced as separate molecules in the host cell.

And prior claim construction proceedings, both in this case and in the Medimmune case, as Your Honor will recall, the focus on this particular claim language had to do with how long the heavy and light chains had to remain as

separate molecules. Could they combine into immunoglobulin or fragment while still in the host cell, or did they have to remain as separate heavy and light chain molecules until they were either expelled from the cell or the cell was lysed and the contents of the cell retrieved?

That was the focus of the argument both in Medimmune and in our *Markman* proceedings in this case last year, but there was never any argument suggesting that the heavy and light chains did not have to be produced and exist as separate molecules at at least one point in time in the host cell.

This is -- in slide 19 we produced a statement from your claim construction order in the Medimmune case where you, again, concluded that the claim language "produced as separate molecules in said transformed host cell" is clear on its face. It requires that something be created, describes the form of that thing at the moment of its creation, and specifies where creation must occur at the moment at which it does.

The language requires nothing more, and the Court offers no further construction. Centocor would agree that that is the plain meaning of this claim language. There has to be a heavy chain produced as a molecule, there has to be a light chain produced as a molecule, and they have to be separate molecules at least for a moment.

Now, Genentech has offered, at the late stage expert reports, a new construction for this, a tripartide construction for "produced as separate molecules," and they said that you have to look at this in the context of the entire claim phrase, which we don't disagree with, but they say you have to look at the "independently expressing" language so that the heavy and light chains are produced as separate molecules

And what do they say? They say, Well, this means three things. It has -- it requires that there be separate mRNAs be produced for the heavy and light chains. That's the requirement for produced as separate molecules. But their expert, Dr. Dolnick, conceded at his deposition -- he was asked, Are heavy and light chain proteins ever encoded by a single messenger mRNA? Answer: No, I can't think of a single instance where that would happen.

So to define something in terms of not being something that never happens anyway simply doesn't make any sense.

THE COURT: Do it again.

MS. ELDERKIN: Sure. They say that "produced as separate" -- the way you determine whether something is produced as separate molecules is that separate mRNAs --

THE COURT: They do say that.

MS. ELDERKIN: -- are produced for the heavy and

light chains.

THE COURT: Yes.

MS. ELDERKIN: Okay. But their expert concedes that that's always the case when you're making an antibody. Are heavy and light chain proteins ever encoded by a single mRNA? No, I can't think of a single instance where that would happen.

So to say that "produced as separate molecules" means you have separate mRNAs is like saying nothing, because that's always the case. You could never have heavy and light chains that are not produced by separate mRNA molecules.

THE COURT: I'm slow.

MS. ELDERKIN: So that cannot be what this means. You cannot -- you cannot say that "produced as separate molecules" means something that must always exist anyway. That doesn't distinguish -- it -- it makes the language perfectly meaningless.

If you're always expressing heavy and light chains with separate mRNAs, then the "produced as separate molecules" language in the claim would be completely superfluous if it means, oh, they're produced by separate mRNAs, because that's always the case.

They set something up that is always the case and say, oh, that's what it means, but that doesn't help any --

in any way in explaining or limiting the claim.

THE COURT: Please, go on.

MS. ELDERKIN: And the next thing that they say is very similar. They say it requires that the heavy and light chains not be linked to one another by a peptide bond.

Now, if you remember the chemistry of these things, the heavy and light chains are polypeptides. They are amino acids that are bounded -- binded to one another in the chain by peptide bonds. So then the chains, the heavy and the light chains, are assembled into an antibody by disulfide bonds, a different kind of bond.

But what they're saying is, oh, it's produced as separate molecules if the heavy and light chains are not linked to one another by a peptide bond. Well, again, their expert conceded that peptide bonds never naturally form between heavy and light chains. That never happens anyway.

So what are you saying about "produced as separate molecules"? You're saying, Well, this is something that never happens anyway. And that's what this means. It's not offering any definition whatsoever.

Now, their expert didn't say this in his deposition, but their counsel, later on in briefing, points to an article that was published many years after Cabilly was filed that purports to discuss a single chain polypeptide; in other words, heavy chains -- heavy and light

chains that might be linked together with one another --

THE COURT: Yes.

MS. ELDERKIN: -- by a peptide bond. But that was published long after Cabilly, and we have to construe the Cabilly claims based on the knowledge at the time Cabilly was filed. So that article does not help them at all. So that second prong of that tripartide construction simply makes no sense.

Then they say, okay, what this means -- what does "produced as separate molecules" mean? Separate regulatory sequences control the expression of heavy and light chains. Their expert also conceded that when have you independent expression, which is also required in this claim here, you have separate regulatory sequences.

So maybe the claim does require separate regulatory sequences to control expression so that you have independent expression, but that doesn't mean that that's defining "produced as separate molecules."

None of the constructions that Genentech has offered makes sense, and certainly none of them reflect the plain meaning of "produced as separate molecules." When you consider the specification and what's really disclosed in the specification, it's quite clear that what the Cabilly inventors meant when they used this language "produced as separate molecules" was just that, that you have a heavy

chain and it's a separate molecule and you have a light chain and it's a separate molecule.

And the reason that's clear from the specification is that's all they tried to do in the specification. You remember, the only real disclosure in that specification is of an example that purports to create immunoglobulin in an in vitro method -- am I still on? All of a sudden I heard something -- in an in vitro method where the heavy chains and light chains were produced in the cell, the cell was lysed, you removed all the other protein stuff, and then you allowed them to combine. But it was very, very clear that heavy and light chains were produced as separate molecules.

There's even a chart in the patent where they measured how much heavy chain was produced and how much light chain was produced. That's what they did. That's the only disclosure in the specification other than their wishful thinking about, gee, an in vivo method might work some day. And that's what we have to base our understanding and our construction of "separate molecules" on.

Genentech also argues in its brief, well, gee, that -- the construction that Centocor is now propounding, which, of course, is the plain-meaning construction, that doesn't align with what our purpose of our invention was. But they don't cite a single case that suggests that the plain meaning of a claim term can be ignored based on some

alleged purpose that a patentee might say either in his specification or in the prosecution history.

So the plain meaning of "produced as separate molecules" is, as I've discussed, a heavy chain has to be produced. It has to be a separate molecule at some point in time. A light chain has to be produced. It has to be a separate molecule at some point in time. We know from your earlier construction, they can start to combine while still in the cell, but they still at some moment in time have to exist as separate molecules.

That's the language they used in the claim. If they didn't want their claim to be so limited, they didn't have to use that language, but that's what they did, and that's what Centocor and the public are entitled to rely upon.

So --

THE COURT: And Centocor doesn't do that?

MS. ELDERKIN: Centocor -- we contend that they cannot prove, they have no proof that that is what Centocor does. And that's where I will go now.

We know that there are several different pathways to antibody assembly in a cell. This particular chart that I have on slide 21 is from -- oops, sorry -- on slide 21 is from Exhibit 30, which is the Baychock (ph) article.

Baychock discussed several different ways in which

heavy chains and light chains can combine in a cell to form an immunoglobulin. And the first one of the pathways that's illustrated here -- and we've circled it in the red box on the slide -- is called the HL pathway.

The HL pathway is one in which the heavy chain -- a heavy chain and a light chain combine to form an intermediate called HL. And, at least as shown in this particular graphic, that HL entity can then meet up with another HL entity to form the tetra -- the full molecule.

What we also know from the literature -- and on slide 22 we show a figure from example -- Exhibit 31, which is the Bergman article. We know that for some antibodies where the HL pathway is followed -- the HL pathway is for assembly -- sometimes light chains start to bond to the heavy chains before the heavy chains are fully produced.

And what this figure -- this is figure A from the article -- is trying to show, the -- at the bottom of the figure here is the endoplasmic reticulum where the light chains and the heavy chains are being produced. And what's shown here is a heavy chain being produced. It's getting longer and longer as more amino acids are being added to the chain.

So this is one heavy chain that's just being shown at different points in time as it's being produced. But as you can see, about two-thirds of the way over towards the

right, you have a heavy chain that's still in production, but it has started -- because it's already bound to a disulfide bond, to a completed light chain. The light chain is shown by that heavy vertical bar.

So before the heavy chain is fully produced as a heavy chain separate molecule, it has already bonded to a light chain. That heavy chain will never exist as a separate molecule.

And why that is important is because for the Centocor antibodies, there's evidence that Genentech cannot dispute that they are antibodies of the type, I-G-G-Y antibodies, that form by the HL pathway, the one I just showed you, which involves heavy chains able to bond to light chains before the heavy chain is completely produced as a separate molecule.

And what we have is, Genentech's infringement expert conceded that for the accused Centocor products, disulfide bond formation occurs between heavy and light chains before the heavy chain is fully translated. Now, he wouldn't concede all the time, but he said at least some of the time that happens. At least some of the time in the Centocor products heavy chains bond to light chains before the heavy chain is fully produced as a separate molecule.

Further, he conceded that he has no evidence in his report to show that heavy and light chain proteins for

the accused products are not chemically bonded together until after they are fully translated. And that's an excerpt from his deposition that I show on this slide. He says, No, I don't have any evidence in the report. I just cite literature.

So where does Genentech go with this? They have their expert admitting that at least some of the time heavy chains are bonded to light chains before they are produced as separate molecules in the Centocor accused processes.

So what do they do? They say, Well, some of the time we -- you infringe because the literature suggests that some of the time, even if you have that HL pathway, that HL intermediate might then bond up with a fully formed heavy chain. So some of your heavy chains might form as separate molecules before they bind up.

Well, there are problems with that argument. First of all, there's a problem with the law. They cite one case, the *Bell Communications* case which only addresses this part-time infringement issue in dicta. It's also a case where it was not a method-of-making claim, like ours. It's was a method-of-using claim.

The accused infringers sold the device which sometimes, when it was used by customers, could follow the patent claim, the method-of-using claim, but sometimes it would not. And in dicta, the Court suggested that that was

something that could be looked at on remand.

But there you had a device, and you could go and you could see what -- what customers were doing. You could see was that device being used according to the claim or not. A yes or no answer was possible. Here there's a total absence of proof that any Centocor process follows anything but the preferred HL pathway, the one I've been discussing, all the time.

Now, the Genentech expert says the HL pathway is not obligate, but he admits it's preferred, and yet he doesn't have any data whatsoever to prove that the Centocor processes do not use the HL pathway all the time. He has only speculation.

He even said in his deposition, Well, there are tests that one could have done. You could done a Western blot test to determine if there were separately produced heavy chains and light chains. He didn't do those tests. All he does is speculate.

And you'll recall from the briefing, his speculation is all over the place. At one point he says, Well, it could be as little as 1 percent of the heavy and light chains that are produced as separate molecules. And then he says, But it could be 90 percent. He simply doesn't know. He has no evidence. They cannot go to the jury with no evidence.

Again, he could not even quantify this alleged occasional infringement, the last point on the slide.

So bottom line, Your Honor, we believe that when the plain meaning of that claim term is applied, as you have instructed now in two cases, that Genentech cannot meet its burden of proof on infringement. And since it cannot meet its burden of proof -- it has no evidence. It has only speculation from its expert and argument from its counsel -- that summary judgment of noninfringement of claim 33 should be granted.

THE COURT: Thank you.

MS. DURIE: Your Honor made reference earlier in the day to an argument having come out of the blue, and this is in fact one such argument.

The Court will recall in the context of the Medimmune claim construction that the question of how to construe this limitation in claim 33 "independently expressing so as to produce the heavy and light chain as separate molecules" was at issue, and Genentech and City of Hope have consistently taken the position that this is one limitation that needs to be understood together, and that the "so that" language is there to make clear that the molecules being produced as separate molecules is simply the consequences of independent expression.

There is independent expression of the heavy and

light chain. The consequence of that independent expression is so that they are produced as separate molecules.

Now, Ms. Eldrikin suggested in her argument with reference to our expert's opinion that this could not be a correct claim construction because in the case of making an antibody in nature, it will always be the case that the heavy and light chain are independently expressed in that sense.

THE COURT: Yes.

MS. DURIE: That is true, but that was not the relevant point of distinction being made here. The point of distinction being made with respect to claim 33 was not over how antibodies are produced in nature. It was over the prior art, and specifically over prior art that did not involve the independent expression of two protein chains but instead prior art such as prior art directed to insulin that involved the expression of a single stranded -- a single strand of protein where you might have more than one gene. But it would be under the same regulatory control; you would have one mRNA transcript and one chain of protein which then might later be cleaved.

That was the critical distinction that is being addressed in claim 33. Whether you are expressing one gene under -- or set of genes under one set of regulatory controls or whether you are independently expressing two

genes, co-expression, that was the critical distinction. And the "so that" language "produced as separate molecules" explains the consequences of that critical limitation.

Now, Centocor's counsel also suggested that the patent specification discussed in the embodiment described therein the idea that heavy and light chain were separately produced and remained as separate molecules for some period of time inside the cell and that that was somehow germane to the invention here.

In fact, however, the embodiment that is described in the specification is one in which heavy and light chain are produced inside an E.coli cell as a mess of protein all bound together.

If you could pull up the '415 patent, column 11, line 15 through about 42 --

THE COURT: I have it here.

MS. DURIE: Very good, Your Honor.

So the portion --

THE COURT: What's the -- wait a minute? What's the cite?

MS. MULLIN: It's column 23, and the relevant portion of the specification begins around line 15. And it begins, To confirm the production of heavy and/or light chains in the transformed cells, and then there is a discussion that continues on column 23, from about line 15

through about 42, that discusses a procedure that takes the protein out of the E.coli cell. There's a re-agent of beta mercaptoethanol that's referred to around line 23. The sample is boiled, and then the individual protein chains are taken out from what previously had been this inclusion body, and there is an examination to see whether heavy and light chain protein had been found within that inclusion body after the sample had been subject to beta mercaptoethanol, a denaturant, to break apart all of the disulfide bonds and to be able to make this assessment about the individual protein chains.

That is not a suggestion that this invention has anything to do with the idea that the individual heavy and light chain remain as separate molecules rather than that they are merely initially coming up different polyribosome sites and are being separately produced, which was, in fact, the point here of the invention.

In fact, it was instructive, I thought, Your Honor, that in the Court's *Markman* work from the Medimmune case, the Court referenced "the moment of creation"; that --

THE COURT: Yes.

MS. DURIE: -- the molecules are produced as separate molecules at the moment of creation. And that is what happens here. We have two separate sites at which polyribosomes attach. We have two separate molecules

formed. At that moment of creation, it is undisputed that they are separate molecules.

THE COURT: Well, I've got to say that if you write that, you will never forget having written it.

MS. DURIE: No doubt, Your Honor.

And I thinks it's important that, one, the idea that these are separate molecules at the moment of creation is entirely consistent with this Court's prior claim construction order from Medimmune.

And that if Centocor had some different understanding of what "produced as separate molecules" meant, it should have raised that as an issue in connection with claim construction rather than waiting to raise it as an issue only now, because it has been apparent throughout that Genentech's understanding of what this claim requires on its face is simply that there be independent expression and that as a consequence of the independent expression, we have two separate protein chains that are formed.

Now, I've discussed the portion of the specification to which Centocor's counsel pointed, which is not addressed to this issue at all. It is interesting to note that the specification does shed some light on the meaning of "molecule" in this context.

If we can take a look at column 13 of the specification, at lines 12 through 14, in discussing

immunoglobulin, the specification states that the tetramer is stabilized intra and intermolecularly by 15 or more disulfide bonds, making clear, even, that in the usage of the specification, the separate chains exist as separate molecules even where there are disulfide bonds intermolecularly and intramolecularly, both within one of the individual given chains of molecule and between them.

Now, Centocor in its briefing had referenced the fact that this language "produced as separate molecules" made its way into claim 21 in connection with the reexamination proceedings and pointed to the same portion of the specification that we had been looking at previously, which was in a relatively long list of citations for the inclusion of the larger phrase and a number of changes that had been made to claim 21.

But I think it's worth noting that one of the other portions of the specification that was referenced in that list of citations is found at column 4. This begins at line 24 and continues on to line 29. And it says as follows: Where the gene is properly inserted with reference to portions which govern the transcription and translation of the encoded DNA message, the resulting expression vector is useful to produce the polypeptide sequence for which the inserted gene codes, a process referred to as expression.

In other words, it's interesting to note that one

of the pieces of support for adding the "produced as separate molecules" language in claim 21 had to do with expression and the idea of expression being under particular transcription and translational control, which is consistent with the view that "independent expression" and "produced as separate molecules," as they are used in -- as they are used in claim 33, joined together by that "so that" language are simply two sides of the same coin.

Unless Your Honor has further questions --

THE COURT: I don't.

MS. DURIE: -- with respect to the claim construction piece of this, let me address the questions about the state of the evidence.

And let me note that Centocor's counsel pointed to one question-and-answer exchange with our expert in which he was asked about whether there was evidence in his report about the showing the heavy and light chain proteins being bonded together, and he said, No, I don't think we present evidence in the report, we just cite literature, well, of course, literature is evidence. He clearly was thinking of evidence in a more experimental sense. And it is, I think, critical in this context to look at that literature.

If we can see Exhibit 30, which is Baychock, at page 7, there are two articles that Centocor showed you in their presentation that they have relied on to attempt to

demonstrate that the heavy and light chain are not produced as separate molecules in the Centocor product.

And let me preface this by saying that, I thought that it was instructive that when the Court asked Centocor's counsel, So your products don't work that way, rather than getting a straightforward yes or no as a response, the response was qualified. And the reason for that is that it is in fact undisputed that much of the time in Centocor's products, even under Centocor's definition, the heavy and light chains will be fully translated prior to any interactions taking place between them.

In Baychock -- if we can pull up in the middle -- if we can blow up in the middle of the screen, this is -- and, actually, if you can get the top chart that Centocor's counsel pointed to, and then go down so we can see it -- no. Can you start with the part that Centocor's counsel pointed to, up with the HL pathway and then go down? Good.

Your Honor, Centocor's counsel pointed to you what appears at the top of the page, where it says H plus L, and then there's an arrow, and it says HL --

THE COURT: Yes.

MS. DURIE: -- that is the HL pathway, and you'll see that there are these different pathways that can be followed for antibody assembly.

What is important here is, if you go a little

further down, and it's two-thirds of the way down the screen, this very article says that although there are preferred pathways of assembly, minor pathways invariably occur. Minor pathways invariably occur.

What we have here is evidence of what happens some of the time; that it may be the case some of the time that heavy and light begin to associate before they are completely translated. But Baychock himself says, as our expert said, and as even Dr. Wall admitted, that there will be instances where that does not happen; where minor pathways are followed; that what we have is different situations taking place, and at least some of the time, the process of claim 33 will be followed such that there will be independent expression of the heavy and light chain and they will be produced as separate molecules.

Bergman is to similar effect. This is the other article on which Centocor relies.

If we can pull up Exhibit 31, and it's at page 18 of Exhibit 31, and if you can blow up the bottom half of that including the text that appears below -- so here again we have the illustration that Centocor's counsel showed you that illustrates that in some circumstances, it is possible that a light chain may begin to associate with a heavy chain before the heavy chain is completely translated.

And if we see the very last sentence in the

explanation of what figure 8 depicts, it says approximately half of the nascent heavy chains form an interchain disulfide bond with a complete light chain before heavy chain completion and release from the polyribosomal complex. So what Bergman is saying here is that this association of heavy and light chain happens about half the time and about half the time it doesn't.

Now, in order to infringe claim 33, what is required is that we have the implementation of a process where we have a heavy chain and a light chain that are independently expressed and the heavy and light chain are produced as separate molecules. The fact that there may be other things that also take place that do not infringe under Centocor's claim construction does not take away from the fact that there is infringing activity even under their definition.

Centocor has not cited any authorities challenging the very well-established proposition that when a process is infringed some of the time, even if that process is not infringed all of the time, the instances of infringement are still infringement. Nothing in claim 33 indicates that it must always be the case.

There is no requirement of always that the heavy and light chain be produced as separate molecules. It requires that this process be followed. And it is in fact

undisputed that with respect to the manufacture of Centocor's products, there are instances in which a first DNA sequence and a second DNA sequence are independently expressed and, even under Centocor's definition, are produced as separate molecules, and that is all that is required for infringement.

Let's go on to the next subject.

MS. ELDERKIN: Your Honor, can I respond to just a few points that Ms. Durie made?

THE COURT: Yes. I -- as I said to you, I've really spent a lot of time thinking about this.

MS. ELDERKIN: We appreciate that, Your Honor. I'll be very brief.

First of all, with respect to Ms. Durie's suggestion that this -- Centocor's position was divulged late in the game --

THE COURT: You can leave that.

MS. ELDERKIN: Okay. Because it's quite remarkable that Genentech can come forward with a complicated tripartide plain-meaning construction of a term that we've already been instructed twice should be construed according to its plain meaning, but -- I guess I'll just go back to, the bottom line is, they have -- the bottom line is, counsel can argue all they want about what the Baychock and the Bergman articles say. And that's all they have, is

counsel's argument, because their expert, Dr. Dolnick, said what's on the screen here.

I asked him, "I'm going to ask you to assume that 'produced as separate molecules,' the language in claim 33, means that the heavy light chains are not chemically bonded together until after they are fully translated -- can you keep that in mind?

"I will try.

"Okay. If that is the case, you did not provide any opinion on infringement in your report, correct?

"Answer: I don't think I addressed that."

And he did not address that. They have no evidence. They have supposition. And it's not for us to come forward and disprove infringement, as counsel seems to suggest. They have to prove infringement, and they have not done so. Even occasional infringement, they have no evidence whatsoever.

If you look at the Baychock and Bergman articles -- I forget which one it is, but one of them shows a Western blot analysis, the kind of analysis you can do to determine how much heavy chain is there, how much light chain, they didn't do that analysis. They could have. They did not.

They have no evidence, and summary judgment should be granted.

Ms. Mullin will address the last motion, Your Honor.

THE COURT: All right.

MS. DURIE: Your Honor, before that, I would like to respond briefly to this point with respect to the infringement motion --

THE COURT: All right.

MS. DURIE: -- because I think it is important to note that Centocor never set forth this new noninfringement theory in any way that was intelligible and allowed us to respond to it. We went through the claim construction process. We prevailed on our construction of "produced as separate molecules."

We wrote a letter to Centocor saying that it appeared to us that they had no noninfringement argument as a result and that they should supplement their noninfringement contentions, and in their supplement they simply recited the claim language, not merely this limitation but in the context of a much larger phrase, and said that they did not infringe, with no explanation.

There was nothing to which our expert could provide a detailed response. They had not cited Bergman or Baychock. He did say in his expert report that it did not matter to his conclusion the ways in which the chains might come together or the type of cell with the type of

immunoglobulin at issue. And then upon seeing the opinions of Centocor's expert, which for the first time articulated this noninfringement theory, which had not been briefed at claim construction, then provided a detailed response at his deposition, addressed those articles, and explained that in his opinion, it was unquestionably the case that there would be, even under Centocor's definition, both heavy and light chain fully translated in some instances prior to there being any interactions.

MS. ELDERKIN: Your Honor, I'm sorry. I have to take a minute to respond to that.

There was a supplemental interrogatory that Centocor served before expert reports that laid out this issue. It was not provided to Dr. Dolnick, their infringement expert. Nonetheless, in his expert report he does address our argument, and at his deposition he said he considered it. He discusses -- that's where he comes up with the argument about, Well, "produced as separate molecules" really means not connected -- where the heavy and light chains are not connected by peptide bonds.

There was no need for Centocor to come forth and tell Genentech, Well, this is what you're going to have to prove in order to prove infringement under the very plain meaning of this claim language. That seems to be what they're suggesting. They had given us no infringement

contentions to suggest they were going to come forward with evidence of this. We were entitled to sit and wait with -- and see what their experts did.

We keyed them into the fact that, you know, there's this issue about separate molecules, and here -- that here's the Baychock article and the Bergman article. They ignored it, and now they're trying to force blame on us somehow for their failure of proof. That just shouldn't wash, Your Honor.

THE COURT: Thank you.

MS. DURIE: Your Honor, could we look at that interrogatory response? I think it's important for the Court to see it.

THE COURT: All right.

MS. DURIE: There were two interrogatory responses. There was one in March. There was one in April. We provided our expert with the one from March. The one from April was the same in relevant respects.

And I think it's important for the Court to see the way that Centocor articulated its theory.

THE COURT: Wait a minute.

Go on.

MS. DURIE: In their interrogatory response, Centocor simply said, Centocor denies that Remicade infringes -- and there's one for each of the products --

infringes the asserted claims and contends that Genentech and City of Hope have failed to offer any evidence, for example, that Remicade contains an immunoglobulin produced using expression plasmids in a host cell line that independently expresses heavy and light chain DNA sequences and produces -- and then can we go over -- heavy and light chains as separate molecules.

They took that entire phrase; that was the sum and substance of their disclosure. They did not tell us about Bergman. They did not tell us about Baychock. We had to wait to receive their expert report in order to learn that information.

And I think, again, most critically, this is a claim construction issue. Both sides believe that their construction is consistent with the plain meaning of the phrase. That happens all the time when the parties contend that the plain meaning supports their claim construction position.

But if Centocor believed it had a noninfringement argument predicated on what this term means, it should have sought clarification as to the meaning of this term, particularly when it was apparent from Genentech and City of Hope's arguments that it believed that "independent expression" and "produced as separate molecules" are implementing the same idea and that "produced as separate

molecules" is simply the consequence of independent expression.

THE COURT: We're not going to go on.

MS. ELDERKIN: Okay. Well, your Honor, if I could just on the record, then, ask you to look at Dr. Dolnick's report, which is Exhibit 27, paragraph 65, where he -- it is his opening infringement report where he expressly addresses Centocor's noninfringement position.

THE COURT: I will do that.

MS. ELDERKIN: Thank you, Your Honor.

THE COURT: Go ahead.

MS. MULLIN: Thank you, Your Honor.

The quid pro quo for patent exclusivity is disclosing your inventive contribution to people in the field. And the written description requirement is meant to ensure that the scope of the right to exclude is limited to the invention that's described in the patent, that it's limited to the contribution it's made to the field as reflected within the four corners of the patent specification.

It is clear from the law that there are some things that are absolutely not sufficient to meet the written description requirement, and two of them are very important to this motion. One is it's not sufficient to say, Here's our goal, our goal is to produce an antibody,

and then to leave it to other people in the field to figure out actually how to accomplish that.

And it's not even sufficient if you provide a description that might make it obvious or enable somebody else in the field to do it. Because the issue of written description is, what does the specification convey that the applicants possessed as part of their invention; were the applicants in possession of the invention that they claim.

So the claim at issue here in Centocor's motion No. 4 is claim 33. This is a claim for a process for producing immunoglobulin molecule. That's the goal. And the issue for written description in the context of claim 33 is, does the specification convey that the Cabilly applicants were in possession of a functioning process of producing antibody.

Identifying that as a goal and leaving it to others to figure out how to do it is not sufficient, even if it would have been obvious to other people in the field how this might have been accomplished. The question is, did the Cabilly applicants possess it and describe it in a way that conveyed that they possessed what they claimed to be part of their invention.

And here the claim is broad, because it encompassed processes where the antibody is assembled in vivo, in the cell, as well --

THE COURT: That's right.

MS. MULLIN: -- as processes where it's assembled in vitro. All we know from the claim is that you have heavy and light chain produced as separate molecules in a single host cell. How and where they are combined is not specified.

So the question here is, does the specification convey that the applicants were in possession and that they invented what they've claimed, which would encompass in vivo and in vitro processes for making an antibody.

So what does the specification -- and, again, the written description test looks at the four corners of the specification to see what is conveyed. And what does the specification say about whether the applicants were in possession of a process for producing antibody in vivo?

They say, Well, when the heavy and light chain are co-expressed in the same host, the isolation procedure is designed to recover reconstituted antibodies. This can be accomplished in vitro, as described below, or might be possible in vivo. "Might be possible in vivo," that's what the specification says.

Even if there's other places in the specification, as defendants argue, that could be interpreted as indicating that in vivo assembly would be preferred, that you might use mammalian host cells for in vivo assembly -- and they are

mentioned -- that really begs the question, because the question for written description is, does the specification convey that the Cabilly applicants possessed the claimed invention of producing an antibody in vivo.

It's not sufficient to just say, Well, there's mammalian host cells that are described that could have done that. People skilled in the art would know that you could use mammalian host cells. It would have been obvious or somebody else could have done it. The dispositive fact here is that the -- what the Cabilly applicants say is that it might be possible, and no --

THE COURT: I must --

MS. MULLIN: -- no reasonable --

THE COURT: -- have looked at those words --

MS. MULLIN: More than once.

THE COURT: -- five hundred times and over a period of years, so I understand what you're talking about.

MS. MULLIN: Right. And no reasonable jury could conclude that when the Cabilly applicants say in their specification that this is only something that might be possible, that they actually possess that process.

And defendants' experts agree. Dr. Scott was asked, did they demonstrate that they actually formed any immunoglobulins inside a host cell. He says, Well, I, you know, would rather say prove than demonstrate, but whatever

it is, they did not demonstrate that they were successfully assembled inside the host cell. And this is dispositive.

The claim encompasses in vivo assembly, and they were not in possession of this aspect of what is claimed, and that's dispositive of the motion. Claim 33 should be declared invalid.

Now, defendants argue that, Well, we showed in vitro assembly. And it's really not Centocor's burden under the law to show that they didn't demonstrate possession of every aspect of what's claimed, only that they didn't demonstrate possession of what's claimed. But even if you say it's Centocor's burden to show that the application does not demonstrate in vitro assembly, we can do that.

So this is actually the process that is described a little bit in the Cabilly specification, and this is what they did. They transformed E.coli with the heavy and light chain genes.

THE COURT: I know.

MS. MULLIN: And as Ms. Durie said, what comes out of that -- I think she called it a mess of protein. I think their expert called it a clump of protein. And what you do, is then you break apart or you lyse the E.coli cells, and you get that clump out of there. And what comes out is actually 99 percent junk protein, we'll call it.

One percent, they approximate, 1 percent of what comes out of the E.coli might be heavy and light chain.

But they take this whole 100 percent of all this protein and they put it through some various processes, some dialysis, and then they take -- actually, two dialysis steps, and they take what comes out of those two dialysis steps, and they put them -- they put the product of that into an ELISA assay.

And the way an ELISA assay works is you take antigen -- in this case they were trying to make anti-CEA antibodies -- they put down CEA antigen. They coat a well with that. And then you put this solution of stuff that came out of the dialysis on top of that, and when stuff sticks -- you add some other stuff, enzymes, et cetera, and when stuff sticks, it changes the color, and then you use the level of color change to approximate how much stuff you have sticking to the bottom of a well.

But the problem is that don't know what is sticking to the bottom of the well. All you know is that you've got a color change because something is sticking. And the defendants' expert admitted that what could be sticking, Well, it could be antibodies, but it could be just light chains, it could be just heavy chains, it could be heavy and light chain fragments, it could be heavy and light chain dimers, it could be aggregates of protein.

So looking at this a little bit graphically, you've got this clump of protein that comes out of the co-transformed E.coli, 99 percent of it is other proteins, 1 percent they approximate to be heavy and light chain. They stick it in the ELISA, and they say -- what they report in the Cabilly patent in column 25 is actually the number .76 percent. That's the number that actually appears in column 25 of the Cabilly patent for reported recombination of the E.coli sample that was co-transformed with heavy and light chain DNA.

But that .76 percent -- and it's not 76 percent. It's .76 percent -- that is that they're getting a signal in the ELISA assay that approximates protein that constitutes .76 percent of the 1 percent that might be heavy and light chains.

So what they're really saying is, we put this whole big glob through the processing, we put it into an ELISA assay, and we have a signal generated by something less than 81 millionths of the protein that came out.

But what's responsible for that signal? You can't tell that there's any antibody there. There's no evidence that there's any antibody there. They could have done some things to test that; and actually they did, but it's not in the patent, and it would prove that they hadn't. But it's not in the patent, and we have to stick with what's in the

patent.

And what the patent doesn't give us is enough information for someone skilled in the art to recognize, to convey to someone skilled in the art that they had actually made any tetrameric antibody.

There is data in column 25 of the patent that gives you a signal for light-chain-only binding, but that's not enough. That would be like saying, Okay. We've got six people in the room and we have a contribution basket in there. And, at the end of the day, we've got 76 cents in the basket. You say, Okay. Ms. Eldriken, how much did you put in? She says, 40 cents. So we know that's what she did. But that doesn't convey that I contributed anything to the 76 cents.

All it says is that there's some protein sticking or there's 76 cents in the bin, and we know that 40 cents of it didn't come from me. We know that came from Ms. Eldriken. But it doesn't convey that I contributed anything, just like what's reported in the Cabilly patent does not convey that there was any tetrameric antibody formed that contributed to that signal.

Now, their expert -- they have offered expert testimony from Dr. Freedman, especially where he says, Well, you know, I think probably it's not all due to something else. It's likely there could be some antibody there. But

what he relies upon for those opinions are things outside the patent.

Look at what Dr. Freedman relies upon in paragraph 60, paragraph 62 of his expert declarations they rely on so heavily. He looks at laboratory notebook pages. He looks at laboratory notebook pages from a non-inventor. He looks at different tests and says, Well, based on all this information, I think probably there's some antibody there. Well, that has zero probative value for the purposes here because that's looking outside the scope of the specification.

They have not proffered any opinion from any expert who looked just within the four corners of the specification, as you're required to do, in assessing written description and can even offer the opinion that based just on that, there is information that conveys the applicants possessed a process for assemblying an antibody in vitro.

So we have a piece of data report from the patent that is .76 percent. That's .76 percent of 1 percent of something that generated a signal. That does not convey, and what our experts have said it does not convey, is evidence that any antibodies were actually formed as a result of the process that is described in the Cabilly patent.

Now, it's true -- I know they're going to get up here and say, We didn't have to provide any example at all. That's not required for written description, that's true. They didn't have to have an actual reduction to practice. But the issue here is that is the only description.

They had one place where they described how you might assemble -- or what a process might be for assembling antibody in vitro, and they didn't show that it worked. And that's the dispositive part on the in vitro assembly; not he whether he had an example or not, because that's not the law, but whether or not, however it's described, they conveyed that the applicants -- that the Cabilly applicants actually had a process where they made antibody, and the answer is no, they did not.

THE COURT: All right. Thank you.

Please.

MS. DURIE: Your Honor, let me begin by framing the question. In Centocor's reply brief at page 5 it says, This is not a case where the issue is whether applicants provided sufficient description of enough species to support a claim to a broad genus.

THE COURT: No, it isn't that.

MS. DURIE: And then they say, Although claim 33 is analogous to a traditional genus claim in its spread, the fault is not in failing to describe sufficient embodiments

or species. Claim 33 is invalid because there is no description of a process that results in an antibody being formed.

We just heard from Centocor's counsel an argument that whether the patent specification adequately describes in vivo assembly ought to be dispositive on the written description question, but that is inconsistent with the argument that Centocor has presented to this Court. It is not an issue that was briefed. It was an issue that was raised, at most, in a footnote to Centocor's reply brief, with no argument, no analysis, merely a statement and a citation to *Ariad*.

The basis on which Centocor brought this motion is that the patent specification does not describe any method of making an antibody, and that is the basis on which the Court should resolve this motion.

Now, having said that, let me turn to the two substantive arguments that Centocor makes. The first has to do with in vivo assembly. Centocor focuses very heavily on the one line from the patent specification, with which we are all very familiar.

If we can pull up column 12, line 50 to 56. Column 12, line 50, and beginning actually at line 53, says, This can be accomplished in vitro, as described below, or might be possible in vivo in a microorganism which secretes

the immunoglobulin chains out of the reducing environment or the cytoplasm.

That is a statement that is specific to microorganisms. It has nothing to do with the question whether in vivo assembly would take place within the mammalian host cells that are elsewhere described in the specification.

And our expert put forward extensive evidence explaining that elsewhere in the specification the patent has disclosures that would be understood by a person of skill in the art as referring to in vivo assembly within mammalian cells.

He testified, for example, that the language at column 8 of the specification, beginning around line 33, which discusses the recovery -- can we -- which discusses the recovery -- column 8, starting at line 33, this discusses the recovery of antibodies from cells and says, It can be either from spun-down whole cells or from a cell culture with both the medium and the suspended cells. He explained, if you're recovering antibody from spun-down whole cells, that is -- the implication is that the antibody has assembled in vivo.

And, likewise, there's a reference in the specification to -- immediately before, actually, the language we were looking at previously, at column 12, it's

around line 48 where it says that tissue culture cells, that is to say mammalian host cells, as hosts also appear, in general, to permit reasonably facile recovery of heterologous protein; again, language that he testified a person skilled in the art would understand as referring to the fact that one would expect to achieve in vivo assembly through the use of mammalian host cells.

Now, Centocor's counsel has agreed Genentech and City of Hope were not required to experimentally demonstrate practicing the invention in each of its potential embodiments, but this language in this specification does demonstrate possession of an invention involving the use of mammalian host cells in which all of the experts, even Centocor's expert, Dr. Wall, are in agreement; that a person of skill in the art through the use of mammalian host cells would have expected in vivo assembly.

That -- that address the in vivo assembly issue. At worst, there is a question of fact raised by our expert testimony as to how a person of ordinary skill in the art would understand the significance of the disclosure. At worst, I would suggest that there is not because their expert is in agreement with us.

Now, the other issue is in vitro assembly.

THE COURT: Yes.

MS. DURIE: And here Centocor appears to be making

two arguments. The first is that the process described in the patent in the actual experiments yield a .7 percent of the theoretical yield of correctly refolded antibody, and, second, that the use of an ELISA assay was not sufficient to prove that antibodies had been formed.

With respect to the first argument, it is important, here again, to note that in their brief, Centocor agreed that, quote, The issue here is not whether the described in vitro process yields a substantial amount of antibody, but whether someone skilled in the field would believe that the inventors were in possession of a process where any antibody was formed as result of the described process.

That is the inquiry as Centocor has framed it. That is correct. And, therefore, the percentage of antibody that was made is not germane to the question.

That takes us to the use of an ELISA assay. Dr. Freedman explained in his report, not with reference to sort of other portions of Dr. Wetzel's lab notebook but from the perspective of a person of skill in the art -- and this is from paragraph 23 of Dr. Freedman's report -- that in April of 1983, immunoassays such as ELISAs were routinely utilized to determine whether denatured -- proteins had been properly reconstituted to their active state. And he then further went on to say that, in fact, current and former

scientists at Centocor testified that this is a common assay used at Centocor to confirm antibody production.

Dr. Freedman did elsewhere in his report carefully review and analyze much of the rest of Dr. Wetzel's and Dr. Perry's notebooks to confirm that antibody -- to make sure that there was nothing in there that undercut the conclusion that antibody in fact was formed. And he did.

But he did not rely on that in reaching this conclusion that the use of the ELISA assay in the Cabilly specification was a well-accepted method of confirming antibody production, and that a person of skill in the art reading the Cabilly specification would have understood it as such.

Now, Centocor's second point here is that it was simply not credible -- strike that. Sorry.

Centocor's second argument here is that a person of skill in the art looking at the ELISA signal would not be able to conclude that that signal was attributable to correctly form antibody because it could be attributable, in part, to other things, and Dr. Freedman could not rule out the possibility that some portion of the signal might, for example, result from a heavy-light chain dimer --

THE COURT: Yes.

MS. DURIE: -- or something else.

THE COURT: Yes.

MS. DURIE: However, in his report Dr. Freedman was very clear that while it was possible that some portion of that signal might be attributable to other things, that did not render the signal as a whole something that was not appropriately viewed as a demonstration of the formation of antibody.

And, in fact, in paragraph 62 of his report, he explained that, In my opinion, it is highly improbable that the measured activity is due solely to nonspecific combinations of heavy and light chains. The generation of antigen recognition activity depends on the correct folding and association of sites in the heavy and light chains, and it is known that correctly folded heavy and light chains form tetrameric immunoglobulin molecules in vitro in accordance with thermodynamic principles of spontaneous self-assembly, citing a paper from 1974.

He goes on to say, I simply do not believe that the activity observed could be entirely due to non-tetrameric molecules.

That testimony, in particular, combined with his testimony that the ELISA assay was recognized at the time as an appropriate way to measure antibody formation, at a minimum creates a disputed issue of fact as to whether the test results shown in the Cabilly specification do -- would have convinced a person of skill in the art that the

inventors were in possession of a method for making antibody.

And I say that notwithstanding that, of course, the specification did not even need to provide those test results, and that in the specification the inventors do repeatedly state that they have invented a process for making immunoglobulin and explain what that process is.

The purpose of the written description requirement is to ensure that the specification defines the metes and bounds of the invention, that it is possible from reading the specification to understand what the inventors invented, and what the inventors -- what is not part of the inventors' invention.

And here the inventors clearly articulated that they had invented a process for making immunoglobulin recombinantly by independently expressing the heavy and light chain, be practiced across a wide range of host cells. Nothing more was required to satisfy the written description requirement, but even to the extent it were, Dr. Freedman's testimony, at worst, creates a disputed issue of fact with respect to how a person of skill in the art would read the description of the test results in the specification.

THE COURT: All right. You will get a decision from us very soon.

MS. MULLIN: One moment, Your Honor. A few

points. One, as to this phrase "might be possible in vivo in a microorganism," just even assuming what Ms. Durie said to be true, the fact that they didn't possess a process for doing this in vivo in a microorganism -- and that is within the scope of claim 33 -- is dispositive as to Centocor's motion. Okay. That is a process that is accomplished within the claim.

In vivo assembly in a microorganism is encompassed within the scope of claim 33, and the best that the Cabilly applicants can say about this is that it might be possible. That does not convey that they were in possession of a process which is part of the invention claimed in claim 33.

There were other parts of the specification that the defendants point to and say, Well, our experts said that people of skill in the art would have understood that you could do this. Again, obviousness is not the test. Enablement is not even the test. And that's hard to grapple with, because you could describe something in a way that is obvious for others to do and you could describe things, and based on what is known in the art others could be enabled to do it, but that's not the question. The question is, is there evidence in the specification that the applicants possessed the invention that's claimed.

Now, on the specifics of Dr. Freedman's expert report, look at paragraph 23 of his report that you've been

referred to, and what Dr. Freedman says is that in April of 1983, and even thereafter, immunoassays such as ELISA were routinely utilized to determine whether denatured and reduced proteins had been properly reconstituted, and he refers to an article by Weidle (ph). And there are cases where it would be proper.

For example, I think -- I haven't looked at Weidle recently, but, as I recall, they were taking antibodies that had been made in vivo and subjecting them to an ELISA assay. Whereas Dr. Freedman admitted during his deposition there would be a natural cell machinery that would perform quality control so that when you're doing the ELISA assay in the context, in that particular context, there is something that can be gleaned from it.

But notice in paragraph 23, he doesn't say anything about the Cabilly specification. He doesn't say anything about the reliability of the ELISA assay and the context of what is described in the Cabilly specification.

And if you look at paragraph 62 of Dr. Freedman's report -- I know it was up on the screen, but it starts by saying, As a result, it's my opinion -- and it goes on and on -- so that he simply does not believe that all the activity observed could be entirely due to non-tetrameric molecules. Well, that's really a wishy-washy statement as to whether or not there's any evidence that there's an

antibody there.

But look at what he's referring to as the "as a result." Look at the preceding paragraph, 61, where he's talking about a laboratory notebook page that includes more data than is included in Cabilly patent. That opinion in paragraph 62 of Dr. Freedman's report, just like the opinion in paragraph 23, don't relate to the disclosure of the Cabilly patent. They relate to other things.

And so they're just not probative, and they can't create a disputed fact about what is disclosed in the specification by having their expert look at things that are outside of the specification, and saying, When I look at all of this other stuff, I have a different opinion. That's not a disputed fact about what is disclosed in the Cabilly patent specification, and it can't be used to defeat summary judgment.

THE COURT: Thank you.

MS. DURIE: May I respond on the first point, Your Honor?

THE COURT: And then we're finished.

MS. DURIE: Centocor's counsel argued that if the patent failed to describe in vivo assembly simply in microorganisms, that that would be a sufficient basis for this Court to resolve this motion. Centocor in its papers made no such argument. We had no opportunity to respond to

that argument.

THE COURT: State it again.

MS. DURIE: Centocor's counsel made an argument that to the extent that the patent specification failed to describe --

THE COURT: That's right.

MS. DURIE: -- in vivo assembly in microorganisms, that that was independently a sufficient basis for this Court to rule. That argument is no where in their brief. We did not have an opportunity to respond to it. That is precisely the genus/species argument that Centocor affirmatively disclaimed in its reply papers.

The question of whether the specification would need to describe in vivo assembly at all was not briefed. Indeed, the claims of the patent are not directed to the way in which assembly takes place. The claims of the patent are directed to a process for producing an immunoglobulin in a host cell and recovering antibody. And the patent specification describes the application of that method across the full range of host cells.

The argument that Centocor is now for the first time trying to make is one that would suggest that Genentech and City of Hope were required to describe every conceivable improvement to the invention, that people might come along and come up with easier ways to practice the invention on

certain types of host cells. So maybe on a microorganism you could skip the step of having to reconstitute the antibody in vitro because you would learn a way for the cell to do it itself in vivo. It's not a claim limitation. It doesn't matter to the practice of the invention. It was not required to say anything.

THE COURT: You're now talking about assembly?

MS. DURIE: Correct, where the -- the mechanism by which assembly happens.

In other words, the inventors teach a way to practice the invention in all host cells. You co-express the heavy and light chain. Protein is formed. You reconstitute the antibody in vitro.

THE COURT: Well, that, of course, is discussed in Medimmune.

MS. DURIE: That's right. And that can be -- that can be practiced across all of the host cells of the invention. That can be done in mammalian cells. That can be done in bacterial cells. It can be done in all microorganisms.

Now, some host cells will make life easier for you and the antibodies will assemble in vivo, and the patent does describe that happening in mammalian cells. But the patentees are not required as a matter of written description law to describe every possible improvement to

the invention that might allow you to short circuit the in vitro assembly process by figuring out how to cause particular types of cells to do that for you.

The written description requirement requires the patentee to describe the invention as claimed. There are not claims specific -- at issue in this case specific to in vivo assembly. Therefore, written description is measured by the scope of the claims, by what is claimed, which is a process for making antibodies across the range of host cells.

And this is -- and, again, the point I want to make here is this is not an issue that was raised by Centocor in this motion. This is not an issue that we briefed. There is a great deal of law that we would be in a position to cite as to why we would not be required to describe the specifics of in vivo assembly with respect to particular types of host cells in order to support the claims at issue here.

THE COURT: I remember discussing the assembly issue some years ago every day for three weeks.

MS. DURIE: That is correct. Because there, there was a claim construction issue presented.

THE COURT: I should say so.

MS. DURIE: Right. And the Court correctly -- I think in this case, correctly concluded that the claims are

not limiting in terms of where assembly takes place.

THE COURT: But there is nothing wrong with their raising this point. It's just that I had to listen carefully to what you were all saying more carefully than I would in any other case because of the many, many discussions there have been in the past about this -- about Cabilly.

One discussion in particular was about assembly. And I cannot say that I have ever once retreated from the position on assembly that we took in Medimmune, and I do remember spending every day for three weeks discussing that issue. I didn't take eight hours a day or ten hours a day, but every day it was discussed again.

Assembly is something that I -- right until today I have never had any reason to retreat from before. I'll think it over now, but I -- that's ground I've already walked on.

MS. DURIE: I understand that the Court has considered the question in the context of claim construction --

THE COURT: Yes, I have.

MS. DURIE: -- as to how the claim should be construed.

THE COURT: Yes.

MS. DURIE: But that is a different question.

THE COURT: That is a different question altogether than the one I just listened to.

MS. DURIE: Correct. And the question whether Genentech and City of Hope would be required to describe separately specific embodiments of the invention with respect to where assembly takes place is not something that was presented by Centocor's motion.

THE COURT: Well --

MS. DURIE: And, indeed, in Centocor's reply brief, they were very clear that the issue here, the issue on which they were proceeding, was whether the patent specification taught any way of making an antibody.

THE COURT: Yes.

MS. DURIE: And that is the basis on which we briefed --

THE COURT: Yes.

MS. DURIE: -- this motion, and that is the basis on which the issues should be --

THE COURT: I understand.

MS. DURIE: -- submitted to the Court.

THE COURT: I understand your point. And I repeat what I said, we'll take it under submission, and you will hear from us quite soon.

Thank you very much. The arguments were quite stimulating, I've got to say.

(Proceedings concluded at 2:03 p.m.)

C E R T I F I C A T E

I hereby certify that the foregoing is a true and correct transcript from the stenographic record of the proceedings in the foregoing matter.

/s/ Bridget R. Montero
Bridget R. Montero
Official Court Reporter
CSR No. 10020

Date: August 20, 2010